

**Avi Garbow/DC/USEPA/US**  
Sent by: Alecia Allston

11/13/2009 09:22 AM

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Rescheduled: Human Studies litigation (Nov 18 03:00 PM  
EST in 4407a)

**Alecia Allston/DC/USEPA/US**

11/13/2009 09:06 AM

To Brenda Mallory

cc "Robin Spriggs"

bcc

Subject Re: Meeting with Avi

done

Alecia Allston  
Staff Assistant  
Deputy Administrator's office  
202-564-0880

Brenda Mallory

[Alecia - I spoke to Avi about getting a m...](#)

11/12/2009 09:07:11 PM

From: Brenda Mallory/DC/USEPA/US  
To: "Alecia Allston" <Allston.Alecia@epamail.epa.gov>  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/12/2009 09:07 PM  
Subject: Meeting with Avi

---

Alecia - I spoke to Avi about getting a meeting on his calendar on the Human Studies litigation. Originally, it was going to be a Background briefing but we now need his input on an issue. Can you schedule something for Wednesday or later with Angela Huskey, Phil Ross, Keith Matthews, Jon Fleuchaus, and me. Thanks.

-----

Sent by EPA Wireless E-Mail Services

**Alecia Allston/DC/USEPA/US**

11/13/2009 09:23 AM

To Brenda Mallory

cc "Robin Spriggs"

bcc

Subject Re: Meeting with Avi

I moved it to 3pm. That's all he has left that day.

Alecia Allston  
Staff Assistant  
Deputy Administrator's office  
202-564-0880

Brenda Mallory [Alecia - I have a conflict at that time tha...](#) 11/13/2009 09:11:43 AM

From: Brenda Mallory/DC/USEPA/US  
To: Alecia Allston/DC/USEPA/US@EPA  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/13/2009 09:11 AM  
Subject: Re: Meeting with Avi

Alecia - I have a conflict at that time that I can not move. Can you find another time. My calendar is up to date. I am free between 11 and 1 and I could also miss the Associates meeting at 3 if I had to. Thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Alecia Allston [done Alecia Allston](#) 11/13/2009 09:06:47 AM

From: Alecia Allston/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/13/2009 09:06 AM  
Subject: Re: Meeting with Avi

done

Alecia Allston  
Staff Assistant  
Deputy Administrator's office  
202-564-0880

Brenda Mallory [Alecia - I spoke to Avi about getting a m...](#) 11/12/2009 09:07:11 PM

From: Brenda Mallory/DC/USEPA/US  
To: "Alecia Allston" <Allston.Alecia@epamail.epa.gov>  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/12/2009 09:07 PM  
Subject: Meeting with Avi

Alecia - I spoke to Avi about getting a meeting on his calendar on the Human Studies litigation. Originally,

it was going to be a Background briefing but we now need his input on an issue. Can you schedule something for Wednesday or later with Angela Huskey, Phil Ross, Keith Matthews, Jon Fleuchaus, and me. Thanks.

-----  
Sent by EPA Wireless E-Mail Services

**Avi Garbow/DC/USEPA/US**  
Sent by: Alecia Allston

11/13/2009 09:06 AM

To  
cc  
bcc  
Subject Human Studies litigation

**Meeting**

Date 11/17/2009  
Time 04:30:00 PM to 05:00:00 PM  
Chair Avi Garbow  
Invitees  
Required Angela Huskey; Brenda Mallory; Jonathan Fleuchaus; Keith Matthews  
Optional  
FYI  
Location 4407a

**Andrew**  
**Simons/DC/USEPA/US**  
05/22/2007 11:33 AM

To Brenda Mallory  
cc  
bcc  
Subject Accepted: Motion to Join EPA in Human Studies Case

**Angela Huskey/DC/USEPA/US**

To Brenda Mallory

cc

08/18/2009 08:53 AM

bcc

Subject Accepted: Human Studies Settlement

**Angela Huskey/DC/USEPA/US**

To Brenda Mallory

cc

05/27/2009 09:25 AM

bcc

Subject Accepted: Human Studies Settlement - Conference Call

**Angela Huskey/DC/USEPA/US**

To Brenda Mallory

cc

06/02/2009 10:36 AM

bcc

Subject Accepted: Human Studies Settlement Conference Call

**Angela Huskey/DC/USEPA/US**

To Brenda Mallory

cc

10/13/2009 10:49 AM

bcc

Subject Accepted: OPPT Interest in Human Studies Settlement

**Angela Huskey/DC/USEPA/US**

To Brenda Mallory

cc

bcc

Subject Invitation: Human Studies Settlement (Aug 18 12:00 PM EDT)

Angela Huskey/DC/USEPA/US

To Brenda Mallory

03/30/2009 12:44 PM

cc

bcc

Subject Fw: NRDC v EPA (human research rule)

Brenda,

Here is the conference line information for the first meeting with the petitioners. I think it's just Keith, you, and me. Is there anyone else that I should forward this to?

Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North

Phone: (202) 564-2892

Fax: (202) 564-5644

----- Forwarded by Angela Huskey/DC/USEPA/US on 03/30/2009 12:43 PM -----

From: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
To: "Wall, Michael" <mwall@nrdc.org>  
Cc: Angela Huskey/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 03/30/2009 12:43 PM  
Subject: NRDC v EPA (human research rule)

---

Michael: EPA would like to discuss settlement with you on Thursday, April 2 at noon eastern time, 9:00 pacific time. (b) (6) Please pass the conference call information on to any of your colleagues who would like to join us.

Thanks. Alan

Angela Huskey/DC/USEPA/US

To Brenda Mallory

01/03/2008 09:54 AM

cc

bcc

Subject Travel for human studies rule hearing

Brenda,

As you know, the human studies rule case is scheduled for a hearing in NYC on January 17 at 10 am. I was planning to travel up there on the evening of the 16th to attend the oral argument. Is that ok? Khisa will be making my travel arrangements.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
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Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

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Phone: (202) 564-2892  
Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

08/17/2009 03:18 PM

To Brenda Mallory

cc "Angela Huskey", "Khisa Lee"

bcc

Subject Re: Settlement

***Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release***

Khisa,

Can you schedule a meeting for Brenda and me to meet tomorrow to discuss the human studies settlement? Please include as optional Phil and Keith.

Thanks,  
Angela

\*\*\*\*\*

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Office of General Counsel, Pesticides and Toxic Substances Law Office  
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Fax: (202) 564-5644

Brenda Mallory

Angela - let's get together tomorrow an...

08/17/2009 03:00:15 PM

From: Brenda Mallory/DC/USEPA/US  
To: "Angela Huskey" <huskey.angela@epa.gov>  
Cc: "Khisa Lee" <lee.khisa@epa.gov>  
Date: 08/17/2009 03:00 PM  
Subject: Settlement

Angela - let's get together tomorrow and discuss the draft settlement agreement. I will be in the office until 3 tomorrow. Thanks.

-----  
Sent by EPA Wireless E-Mail Services

**Angela Huskey/DC/USEPA/US**

01/31/2010 09:43 PM

To Brenda Mallory, Bruce Rodan, Dennis Utterback, Donald Rodier, Ernest Falke, Iris Camacho, Jennifer Wills, John Carley, Keith Matthews, Kelly Sherman, Lee Tyner, Oscar Hernandez, Philip Ross, Warren Lux, William Jordan

cc Fred Hauchman, Jim Jones, Kevin Teichman, Paul Anastas, Wendy Cleland-Hamnett

bcc

Subject Discuss human studies reg text

**Meeting**

Date 02/01/2010

Time 02:00:00 PM to 03:00:00 PM

Chair Angela Huskey

Invitees

Required Brenda Mallory; Bruce Rodan; Dennis Utterback; Donald Rodier; Ernest Falke; Iris Camacho; Jennifer Wills; John Carley; Keith Matthews; Kelly Sherman; Lee Tyner; Oscar Hernandez; Philip Ross; Warren Lux; William Jordan

Optional Fred Hauchman; Jim Jones; Kevin Teichman; Paul Anastas; Wendy Cleland-Hamnett

FYI

Location

I'd like to try to wrap things up with regard to the regulatory language we would be presenting to the petitioners in the human studies case. Please call the following conference line if you're available to participate in this call:

(b) (6)

A large black rectangular redaction box covers the content of the email body following the "(b) (6)" label.

**Angela Huskey/DC/USEPA/US**

02/17/2010 10:46 AM

To Brenda Mallory, Charlotte Bertrand, Lesley Schaaff

cc

bcc

Subject Information Update - Room has changed: Discuss human studies settlement

**Angela Huskey/DC/USEPA/US**

02/17/2010 10:45 AM

To Brenda Mallory, Charlotte Bertrand, Lesley Schaaff

cc

bcc

Subject Rescheduled: Discuss human studies settlement (Feb 17  
11:30 AM EST in Conf Rm 7500/DC-Ariel Rios-OGC@EPA)

Angela Huskey/DC/USEPA/US

To Brenda Mallory, Keith Matthews

05/14/2009 08:07 PM

cc

bcc

Subject Fw: human testing rule challenge - settlement communication

FYI....

\*\*\*\*\*

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Washington, D.C. 20460

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Fax: (202) 564-5644

----- Forwarded by Angela Huskey/DC/USEPA/US on 05/14/2009 08:05 PM -----

From: "Wall, Michael" <mwall@nrdc.org>  
To: <Alan.Greenberg@usdoj.gov>, Angela Huskey/DC/USEPA/US@EPA  
Cc: "Jan Hasselman" <jhasselman@earthjustice.org>, "Virginia Ruiz" <vrui@farmworkerjustice.org>, "Colangelo, Aaron" <acolangelo@nrdc.org>  
Date: 05/14/2009 04:58 PM  
Subject: human testing rule challenge - settlement communication

---

Confidential Settlement Communication Subject to FRE 408

Alan:

Petitioners' counsel are prepared to recommend to their clients the following approach to several questions that EPA raised during our last settlement call and in a subsequent exchange of emails. We have discussed these issues with some of our clients, but have not been able to close the loop with all of them.

- 1) We believe that any decision that EPA has made that relied on the proposed rule should be reconsidered. However, we understand EPA's workload concern. We therefore propose a compromise under which, after the new rule is finalized, EPA would revisit DDVP, amitraz, and aldicarb. The parties would reserve their rights with respect to future challenges to other decisions that relied on the proposed rule.
- 2) We believe that EPA should apply the scientific standards of the revised rule to its prospective use of intentional dosing human toxicity studies involving pesticides -- regardless of when those studies were conducted. There is no justification for not applying the highest scientific standards to EPA's ongoing decision making. EPA should, therefore, apply the new rule's scientific standards when the Agency revisited DDVP, amitraz, and aldicarb.
- 3) We believe that EPA should apply the NAS's proposed standard on ethics (Recommendation 5-7) to EPA's prospective use of old human studies (regardless of when those studies were conducted). Specifically, EPA should delete the word

“significantly” before “deficient” in sec. 26.1704 of the Rule. EPA should, accordingly, apply the NAS Rec. 5-7 standard when the Agency revisits its DDVP, amitraz, and aldicarb decisions.

4) We believe that EPA should agree to enforceable deadlines. Separate deadlines would be set out for a proposed rule, a final rule, and for revisiting DDVP, amitraz, and aldicarb. These interim deadlines would lead to completion of each interim step as quickly as possible, and all work (including revisiting the three pesticides) would be completed before January 2013. By way of compromise, that is a later end date than we had originally contemplated.

Before we propose more specific interim deadlines we would like to hear EPA's views on what milestone dates it could meet, consistent with the overall schedule set out above. We understand EPA's workload concern, but we think the workload is manageable, given EPA's existing and deep familiarity with the comparatively narrow issues it would address in the new rule. EPA took less than five month to convert its proposed human testing rule (Sept 2005) into a final rule (Feb 2006); the issues here are narrower.

Please be aware that we are concerned that EPA could make new pesticide decisions, in reliance on the existing human testing rule, before a revised rule is finalized. We would like to hear EPA's thoughts on how to address this concern. We would, at the very least, likely need to reserve our rights, in any settlement, to challenge the validity of the existing human testing rule in any decision that EPA might subsequently make in reliance on that rule, before a new rule is finalized.

Each of these issues is extremely important to petitioners. We look forward to speaking with you once we have a new meeting schedule.

Michael E. Wall  
Senior Attorney

Natural Resources Defense Council  
111 Sutter Street, 20th Floor  
San Francisco, CA 94104  
Phone: 415.875.6100  
Fax: 415.875.6161

---

PRIVILEGE AND CONFIDENTIALITY NOTICE

This message is intended only for the intended recipients. It may contain information that is privileged, confidential, and exempt from disclosure under law. If you believe you may have received this message in error, please notify me immediately by email and delete the original message.

**Angela Huskey/DC/USEPA/US**

To Brenda Mallory, Keith Matthews

cc

04/19/2007 08:37 AM

bcc

Subject Human Studies litigation

FYI....I spoke with Alan (DOJ attorney) about possible oral argument dates for the human studies litigation. He says that the Second Circuit's schedule is already booked through May. And with summer recess coming up, it is possible we won't have a date for oral argument until the fall.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

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Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

02/09/2010 04:13 PM

To Brenda Mallory, Keith Matthews, Chris Kaczmarek

cc

bcc

Subject Fw: Human Research Rule

FYI...

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
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Fax: (202) 564-5644

----- Forwarded by Angela Huskey/DC/USEPA/US on 02/09/2010 04:02 PM -----

From: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
To: Angela Huskey/DC/USEPA/US@EPA  
Date: 02/09/2010 03:47 PM  
Subject: FW: Human Research Rule

---

FYI

**From:** Wall, Michael [mailto:mwall@nrdc.org]  
**Sent:** Tuesday, February 09, 2010 1:46 PM  
**To:** Greenberg, Alan (ENRD)  
**Subject:** Re: Human Research Rule

We have had a bit of delay due to weather ourselves. I'll see what I can do.

---

**From:** Greenberg, Alan (ENRD)  
**To:** Wall, Michael  
**Sent:** Tue Feb 09 12:39:23 2010  
**Subject:** Human Research Rule  
CONFIDENTIAL SETTLEMENT COMMUNICATION

Michael:

When we last spoke, I understood that Petitioners intended to submit alternate language to address EPA's concerns about the overbreadth of the definition of "pesticide." Even though the government in DC is closed due to weather, Angela and others are working from home and await your response on this issue.

Thanks. Alan

Angela Huskey/DC/USEPA/US

To Brenda Mallory, Keith Matthews, Philip Ross

07/20/2009 02:41 PM

cc

bcc

Subject Fw: human testing rule - FRE 408 Communication

For today's call...

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

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----- Forwarded by Angela Huskey/DC/USEPA/US on 07/20/2009 02:41 PM -----

From: "Wall, Michael" <mwall@nrhc.org>  
To: "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>  
Cc: Angela Huskey/DC/USEPA/US@EPA, <jhasselman@earthjustice.org>, <vrui@farmworkerjustice.org>  
Date: 07/20/2009 02:40 PM  
Subject: human testing rule - FRE 408 Communication

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Settlement Communication \*\*\* Subject to Fed. R. Evid. 408

Alan:

We would like to discuss certain language on the call. Rather than redoing the whole redline / strikeout, I have pasted the new language below.

Section 26.1603(c)

Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Administrator shall consider Recommendation 4-1 and the rationale of the National Research Council in developing that recommendation as contained in its report entitled Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues (2004).

Section 26.1705(c)

**Except as provided in Sec. 26.1706, EPA shall not rely on data from any research, unless EPA has adequate information to determine that the research was conducted in substantial compliance with** ~~In determining whether research was conducted in substantial compliance with paragraph (b), EPA shall consider the extent to which any deficiencies in the ethical conduct of the study, including any deficiencies relative to the~~

~~elements contained in~~ section 26.1603(c)(4) through (10), **did not** placed participants at increased risk of harm (based on knowledge available at the time the study was conducted), **and did not** ~~or impaired~~ their informed consent.

Angela Huskey/DC/USEPA/US

12/15/2009 11:11 AM

To Brenda Mallory, Keith Matthews, Philip Ross

cc

bcc

Subject Fw: NRDC v EPA (human research rule)

***Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release***

FYI...

\*\*\*\*\*

Angela M.D. Huskey  
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----- Forwarded by Angela Huskey/DC/USEPA/US on 12/15/2009 11:10 AM -----

From: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
To: "Jan Hasselman" <jhasselman@earthjustice.org>, "Wall, Michael" <mwall@nrdc.org>, <vrui@farmworkerjustice.org>  
Cc: Angela Huskey/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA  
Date: 12/14/2009 06:50 PM  
Subject: RE: NRDC v EPA (human research rule)

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#### CONFIDENTIAL SETTLEMENT COMMUNICATION SUBJECT TO FRE 408

Jan, Michael, Virginia:

We understand petitioners' desire to make enforceable the provisions of paragraph 3 and 4 of the draft settlement agreement (as attached to my e-mail of November 24, 2009) relating to aldicarb and amitraz. However, as I mentioned in my last e-mail, EPA cannot agree to make these discretionary actions enforceable through a consent decree or other form of judicially enforceable document.

A petition for review of an agency action places at issue only the legality of the challenged agency action. For this reason, most settlement agreements that resolve petitions for review address potential changes to the challenged rule and do not establish additional agency obligations. In this case, petitioners specifically requested that the Agency revisit the chemicals amitraz and aldicarb in light of any amendments to the human research rule. EPA, in response, offered to address those two pesticides in the manner set forth in paragraphs 3 and 4, in an effort to try to reach a settlement with petitioners in this case. Because the actions contemplated by paragraphs 3 and 4 are fully discretionary and not subject to any statutory deadlines, they cannot be judicially enforceable under the Meese memo guidelines. Thus, the draft settlement agreement does not make judicially enforceable those actions

EPA intends to take with regard to these chemicals.

In addition, because paragraphs 3 and 4 address matters peripheral to the challenge to the human research rule, there is no feasible non-judicial remedy to provide in this case. As previously explained, the sole remedy available under the Meese memo in this type of litigation is the opportunity to revive the litigation. If EPA issues a new human research rule that triggers the obligations of paragraphs 3 and 4, and then fails to perform those obligations, it makes little sense to provide as a remedy the opportunity to revive the challenge to the original human research rule. At that point in time, the original rule is moot. Further, this case, unlike the DDVP litigation, does not involve a challenge to any final agency action related to aldicarb or amitraz, so there is no pesticide-specific agency action that can be revived as a remedy in the event EPA does not perform the obligations set forth in paragraphs 3 and 4. If Petitioners become dissatisfied with EPA's actions under Paragraphs 3 and 4, they can, if they choose, petition under the FFDCA to revoke aldicarb and/or amitraz tolerances based upon the amended human research rule.

EPA suggests that we try and schedule before the holidays a conference call to discuss these and any other remaining issues.

Alan

**From:** Jan Hasselman [mailto:jhasselman@earthjustice.org]  
**Sent:** Friday, December 11, 2009 2:44 PM  
**To:** Greenberg, Alan (ENRD); Wall, Michael; vruiz@farmworkerjustice.org  
**Cc:** huskey.angela@epa.gov; fleuchaus.jonathan@epa.gov  
**Subject:** RE: NRDC v EPA (human research rule)

COMMUNICATION SUBJECT TO FED. R. EVID. 408

Alan, thank you for taking the time to put together this response.

We think we've made some real progress on working together towards a new rule and would like to see that moving. We are even prepared to recommend to our clients that we agree to your enforcement approach with respect to the adoption of a new rule, as discussed below.

Our primary concern at this point is with respect to aldicarb and amitraz. (As you know, DDVP is subject to a separate lawsuit. While it may make sense to coordinate any settlements, we also recognize that would require further discussion.) If EPA solicits and obtains the recommendations of the HSRB with respect to EPA's reliance on those studies, and the HSRB recommends that EPA should NOT have relied on those studies, there is nothing in this agreement that compels EPA to act on this information until the next reregistration review – which could be more than a decade away. That is an entire generation of children being exposed to chemicals at levels that were not properly set. We are well within our rights to expect faster action than that, and I certainly hope that EPA would want to take faster action.

Moreover, the enforcement approach laid out in the memo provides us with no remedies at all

with respect to the reconsideration of these chemicals. If the case is dismissed at the time that a new rule comes out, we would have no effective remedy under the settlement if EPA were to fail to solicit the views of the HSRB, fail to make a determination that reliance on those studies was unwarranted, or fail to take action on such a determination.

As I read your note below, the distinction between the ESA consent decrees and the "Meese memo" approach that your Section prefers here comes down to EPA's willingness to agree to the substance of the human testing rule up front. When it comes to the reregistration review, however, we are asking for a deadline for reconsidering the standards set for these chemicals.

It seems to us that we could approach this in a hybrid format, and we would be willing to recommend to our clients the following settlement approach: a) adoption of a "settlement agreement" as per your preference for the adoption of a new rule and the other terms that we've been discussing; b) execution of a binding consent decree (or a stipulation of dismissal incorporating an order that the Court would retain jurisdiction to enforce) setting out what is currently included in paragraph 3 and 4 of the settlement agreement, with a change to include deadline for initiating and completing reregistration review IF the HSRB recommends or EPA determines that reliance on the studies was not acceptable. Those deadlines would become enforceable.

I expect we will uncover some additional complexities if we pursue this approach, but I do think it is fair for us to expect that EPA take action on these chemicals if the experts find that the current levels inappropriately relied on human testing studies.

We look forward to hearing from you,

Jan, Michael and Virginia

---

**From:** Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]  
**Sent:** Tuesday, December 08, 2009 12:17 PM  
**To:** Wall, Michael; Jan Hasselman; vruiz@farmworkerjustice.org  
**Cc:** huskey.angela@epa.gov; fleuchaus.jonathan@epa.gov  
**Subject:** NRDC v EPA (human research rule  
CONFIDENTIAL SETTLEMENT COMMUNICATION

Counsel:

We reviewed the three stipulated settlement agreements forwarded by Jan Hasselman. These agreements reflect settlements under a different statute and employ a different settlement structure than what EPA and DOJ typically utilize for the settlement of petitions for review. Even if we were to discuss the use of aspects of these three settlement agreements in our case, the changes that would be required to the framework we have negotiated thus far would be so significant that EPA doubts that it could form the basis of a settlement acceptable to petitioners.

All three agreements Jan forwarded resolve claims under the Endangered Species Act (ESA) and reflect the particular statutory obligations, including deadlines, under Section 3 of that Act. The settlement agreements are based upon a format developed by the Wildlife and Marine Resources Section of DOJ to address these specific types of cases. In contrast, petition for review settlements use a standard format developed by the Environmental Defense Section of DOJ that contain a description of intended agency action but do not provide for enforceable remedies, consistent with the “Meese memo.” We noted that Petitioners did not forward any “enforceable” settlements involving petitions for review, even though DOJ and EPA have negotiated numerous settlements of petition cases with NRDC and Earthjustice attorneys over the past decades.

More important to the issue of enforceability, the three ESA settlements are structured in a materially different way from the approach we have been discussing to resolve the challenges to the human research rule. The ESA settlements contemplate that the federal agency will re-open/reconsider a decision on a specified timetable, but the agreements do not contain any new substantive provisions regarding the content of the agency decision. The litigation case is dismissed upon execution of the agreement. If EPA were to follow the ESA format to resolve your petitions for review, the settlement would provide:

1. EPA would initiate APA rulemaking to propose amending the human research rule, but would not agree to include the language contained in Exhibit A.
2. EPA would take final action on its proposal to amend the human research rule.
3. There would be no provisions for review of specific human studies previously relied upon by EPA in assessing the risk of various pesticides (*e.g.* , Paragraphs 3, 4, and 5)
4. The deadlines for issuance of the proposal and taking final action would be enforceable.
5. Petitioners would dismiss their petitions for review upon execution of the settlement agreement.

In contrast to this ESA format, in our negotiations Petitioners demanded that EPA identify the substance of the proposed amendments to the human research rule (Exhibit A), demanded that dismissal of the case be contingent on the promulgation of a final rule “as substantially contained in Exhibit A,” and demanded that EPA agree to reevaluate, under the revised human research rule, specific human studies conducted with various pesticides. Given the importance Petitioners place on the language agreed upon in Exhibit A and the reevaluation of specific human studies, EPA assumes that a settlement that does not contain those provisions would not provide a basis to settle the petitions for review. However, if the Exhibit A language or the reevaluation of specific human studies is included in the agreement, the Meese memo policies mandate that the obligations not be enforceable.

We look forward to discussing with you a form of settlement agreement that will bring these negotiations to conclusion.

Alan

Angela Huskey/DC/USEPA/US

To Brenda Mallory, Keith Matthews, Philip Ross, Chris Kaczmarek

02/02/2010 09:40 AM

cc

bcc

Subject Fw: Humane research rule

FYI...

\*\*\*\*\*

Angela M.D. Huskey  
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Phone: (202) 564-2892  
Fax: (202) 564-5644

----- Forwarded by Angela Huskey/DC/USEPA/US on 02/02/2010 09:40 AM -----

From: "Wall, Michael" <mwall@nrdc.org>  
To: "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>  
Cc: Angela Huskey/DC/USEPA/US@EPA  
Date: 02/01/2010 07:11 PM  
Subject: RE: Humane research rule

---

I will need to discuss these changes with the various petitioners. In the meantime, Alan, I've had a further thought regarding how to address EPA's concern with the reservation of rights. Call if you want to discuss.

---

**From:** Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]  
**Sent:** Monday, February 01, 2010 3:07 PM  
**To:** Wall, Michael  
**Cc:** huskey.angela@epa.gov  
**Subject:** Humane research rule

CONFIDENTIAL SETTLEMENT COMMUNICATION

Michael:

As we discussed last week, EPA believes that the definition of pesticide in the July version of the regulatory language, which included substances that were ingredients in a pesticide as well as metabolites and degradates, has broad unintended consequences across the Agency. There are a number of substances that may be ingredients in a pesticide or may sometimes be pesticides themselves in some circumstances that might be swept into this rule, even though they were not pesticides in the human studies themselves. One example is a study in which exposure to formaldehyde is being tested with human

subjects. Sometimes formaldehyde is used in pesticides, but it has a lot of other general chemical uses outside the pesticidal context. Studies involving the use of formaldehyde may or may not be using formaldehyde as a pesticide in the study and may or may not be testing the substance for pesticidal purposes. On the other hand, EPA wants to make sure that it is not narrowing the definition such that studies involving substances that are always pesticides are excluded somehow because of how the study is conducted (e.g., putting a pesticide in a capsule to test effects). EPA believes that the current draft refocuses the language on ensuring that the actual studies involving intentional exposure of humans to pesticides themselves are covered by the regulation without unnecessarily sweeping in other chemicals that have multiple uses.

I have attached a copy of EPA's red-lined version of Exhibit A to address EPA's concern in a manner that EPA believes will not adversely impact Petitioners' interests.

I will call you to discuss next steps.

Alan

**Angela Huskey/DC/USEPA/US**

02/03/2010 04:15 PM

To Brenda Mallory, Keith Matthews, Philip Ross, Chris Kaczmarek, Jim Jones, Steve Owens, Avi Garbow, Scott Fulton, William Jordan, John Carley, Kelly Sherman, Steven Bradbury

cc

bcc

Subject The motion to extend stay in human studies case until March 4, 2010 was filed n/m

Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release

\*\*\*\*\*

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Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To Brenda Mallory, Keith Matthews, Philip Ross, Chris Kaczmarek, Jonathan Fleuchaus

02/24/2010 10:13 AM

cc

bcc

Subject Fw: Human research rule

FYI...

\*\*\*\*\*

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----- Forwarded by Angela Huskey/DC/USEPA/US on 02/24/2010 10:13 AM -----

From: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
To: "Wall, Michael" <mwall@nrdc.org>, "Jan Hasselman" <jhasselman@earthjustice.org>, "Virginia Ruiz" <vrui@farmworkerjustice.org>  
Cc: Angela Huskey/DC/USEPA/US@EPA  
Date: 02/23/2010 05:25 PM  
Subject: Human research rule

---

CONFIDENTIAL SETTLEMENT COMMUNICATION FRE 408

Counsel:

I received Michael's message on Friday suggesting that "FIFRA and FFDCA" be changed to "FIFRA and/or FFDCA" in section 26.1301(b). EPA thinks the simpler change is to use an "or" rather than "and/or." The same language appears in 26.1701, so EPA proposes to make the same change in that section. Finally, because neither FIFRA nor FFDCA are defined, EPA suggests stating the full names of the statutes. As a result, EPA proposes:

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA after [insert effective date of amended rule] either of the following:

- (a) a report containing the results of any human research on or with a pesticide for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA.
- (b) a report containing the results of any human research for consideration in connection with an action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y) or section 408 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. § 346a).

§ 26.1701 To what does this subpart apply?

- (a) Except as provided in paragraph (b), this subpart applies to EPA's decisions whether to rely, in actions taken under any regulatory statute it administers, on scientifically valid and relevant data from research involving intentional exposure of human subjects to a pesticide.
- (b) In actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 346a), this subpart applies to EPA's decisions whether to rely on scientifically valid and relevant data from research involving intentional exposure of human subjects.

Regarding paragraph 6, EPA proposes:

Any challenge to any amendments to the 2006 final rule must be brought in a new action and Petitioners reserve whatever rights they may have to bring such a challenge, except as specifically provided below. Notwithstanding the foregoing sentence, if EPA amends the 2006 final rule by adopting the language of Exhibit A without making any material changes to the language of Exhibit A, Petitioners will not exercise whatever rights they may have to seek judicial review of those amendments pursuant to 21 U.S.C. § 346a(h)(1) or otherwise. Nothing in this settlement agreement shall restrict Petitioners' rights to comment on or otherwise participate in the APA rulemaking discussed in paragraph 1.

EPA understands that Petitioners are agreeing to the rule revisions as a package. However, Petitioners' suggested precondition -- that EPA "makes no other amendments to the 2006 final rule" -- is likely an impossible condition to satisfy. As you know, the proposed amendment will be subject to APA notice and comment rulemaking. EPA will likely make at least one change in response to comments received. If the change is immaterial to the package (e.g. using a full statute's name rather than an acronym), the change should not provide a basis for Petitioners to challenge the amendments. We think "material changes" protects Petitioners' position without establishing a standard that EPA cannot realistically meet.

We look forward to your response.

Alan



**Angela Huskey/DC/USEPA/US**

11/09/2009 02:43 PM

To Brenda Mallory, Keith Matthews, Philip Ross

cc Robert Perlis

bcc

Subject Discuss human studies settlement

**Meeting**

Date 11/12/2009

Time 11:30:00 AM to 12:00:00 PM

Chair Angela Huskey

Invitees

Required Brenda Mallory; Keith Matthews; Philip Ross

Optional Robert Perlis

FYI

Location Brenda's office

**Angela Huskey/DC/USEPA/US**

11/09/2009 02:46 PM

To Brenda Mallory, Keith Matthews, Philip Ross

cc Robert Perlis

bcc

Subject Rescheduled: Discuss human studies settlement (Nov 10  
03:30 PM EST in Brenda's office)

**Angela Huskey/DC/USEPA/US**

11/09/2009 03:07 PM

To Brenda Mallory, Keith Matthews, Philip Ross

cc Robert Perlis

bcc

Subject Rescheduled: Discuss human studies settlement (Nov 12  
11:30 AM EST in Brenda's office)

Angela Huskey/DC/USEPA/US

06/22/2009 01:28 PM

To Brenda Mallory, Keith Matthews, Philip Ross, William Jordan,  
John Carley, Kelly Sherman, Jim Jones, Debbie Edwards  
cc  
bcc  
Subject Fw: NRDC v EPA human research rule: 2nd cir. extended  
the stay

FYI...

\*\*\*\*\*

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----- Forwarded by Angela Huskey/DC/USEPA/US on 06/22/2009 01:27 PM -----

From: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
To: Angela Huskey/DC/USEPA/US@EPA  
Date: 06/22/2009 01:26 PM  
Subject: NRDC v EPA human research rule: 2nd cir. extended the stay

---

The stay is extended to August 4, 2009.

Alan

Angela Huskey/DC/USEPA/US

07/27/2009 02:03 PM

To Brenda Mallory, Philip Ross, Keith Matthews, William Jordan,  
John Carley, Kelly Sherman

cc

bcc

Subject Fw: FRE 408 Communication -- human subjects rule

FYI

\*\*\*\*\*

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Fax: (202) 564-5644

----- Forwarded by Angela Huskey/DC/USEPA/US on 07/27/2009 02:02 PM -----

From: Angela Huskey/DC/USEPA/US  
To: "Wall, Michael" <mwall@nrdc.org>, Jan Hasselman <jhasselman@earthjustice.org>, Virginia Ruiz <vruiz@farmworkerjustice.org>  
Cc: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
Date: 07/27/2009 02:02 PM  
Subject: FRE 408 Communication -- human subjects rule

---

Michael,

For our discussion this afternoon, here is EPA's response to your suggestions for 26.1705(c). We found your revisions to 26.1603(c) as contained in your email of 7/20/09 acceptable.

(c) Except as provided in Sec. 1706, EPA shall not rely on data from any research, unless EPA determines that the research was conducted in substantial compliance with one of the following:

(1) a proposal that was found to be acceptable relative to the elements contained in section 26.1603(c) and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under section 26.1603(c), EPA shall not rely on that data.

(2) a proposal that would have been found acceptable relative to the elements contained in section 26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
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Angela Huskey/DC/USEPA/US

To Chris Kaczmarek

11/29/2010 09:35 AM

cc

bcc

Subject Re: human studies case files

Yes.

\*\*\*\*\*

Angela M.D. Huskey  
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Chris Kaczmarek [Are you the keeper of the case files a...](#)

11/23/2010 10:15:27 AM

From: Chris Kaczmarek/DC/USEPA/US  
To: Angela Huskey/DC/USEPA/US@EPA  
Date: 11/23/2010 10:15 AM  
Subject: human studies case files

---

Are you the keeper of the case files again for human studies? Two items from the Court came in the mail for Keith that should be filed away in the case files. Thanks, Chris!

Angela Huskey/DC/USEPA/US

To Grant MacIntyre

03/10/2010 09:49 AM

cc

bcc

Subject Re: EAJA settlement question

*Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release*

I'm working from home today. Could you please call me for this meeting? (b) (6) Thanks!

\*\*\*\*\*

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Grant MacIntyre Jon: Can you send a copy of the settle... 03/09/2010 04:09:38 PM

## Re: EAJA settlement question

Wed 03/10/2010 2:30 PM - 3:00 PM

Attendance is for Angela Huskey

Chair: Grant MacIntyre/DC/USEPA/US

Rooms: Conf Rm 7428/DC-Ariel Rios-OGC@EPA

Required:	Jonathan Fleuchaus/DC/USEPA/US@EPA
Optional:	Angela Huskey/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA

### Description

Jon:

Can you send a copy of the settlement agreement (if available)?

Thanks,  
Grant

do you have some time tomorrow when we could talk briefly? thanks

Grant MacIntyre

Chris: I am one of the EAJA cont...

03/09/2010 04:03:19 PM

From: Grant MacIntyre/DC/USEPA/US  
To: Chris Kaczmarek/DC/USEPA/US@EPA  
Cc: Daniel Schulson/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, James Drummond/DC/USEPA/US@EPA, Sonja Rodman/DC/USEPA/US@EPA  
Date: 03/09/2010 04:03 PM  
Subject: Re: EJA

---

Chris:

(b) (5)

A large black rectangular redaction box covering several lines of text.

Thanks,

Grant B. MacIntyre  
U.S. EPA Office of General Counsel  
Cross-Cutting Issues Law Office (CCILO)  
(202) 564-6165

(b) (5)

A large black rectangular redaction box covering a significant portion of the email body.

---

Personal Notes

---



**Angela Huskey/DC/USEPA/US**

04/10/2009 09:27 AM

To Jim Jones, William Jordan, John Carley, Kelly Sherman,  
Byron Brown  
cc Keith Matthews, Brenda Mallory, Jonathan Fleuchaus, Philip  
Ross

bcc

Subject Motion for stay in human studies case

The motion for stay in NRDC v. EPA is being filed in the Second Circuit today.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
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Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

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Phone: (202) 564-2892  
Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To Jonathan Fleuchaus

02/25/2010 01:23 PM

cc

bcc

Subject Fw: Human Studies Settlement - OMB Interface

Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release

\*\*\*\*\*

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----- Forwarded by Angela Huskey/DC/USEPA/US on 02/25/2010 01:23 PM -----

### Human Studies Settlement - OMB Interface

Thu 02/25/2010 4:30 PM - 5:30  
PM

Attendance is for Angela Huskey

Chair: **Avi Garbow/DC/USEPA/US**

Sent By: **Monique Patrick/DC/USEPA/US**

Location: 4045 AR Rooms: Room 4045/DC-Ariel Rios-OGC@EPA

Required:

Angela Huskey/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Charlotte  
Bertrand/DC/USEPA/US@EPA, Eric Schaaf/R2/USEPA/US@EPA, Jim  
Jones/DC/USEPA/US@EPA, Lisa Heinzerling/DC/USEPA/US@EPA

Description

---

**Personal Notes**

---

Angela Huskey/DC/USEPA/US

07/08/2009 09:33 AM

To Keith Matthews, Brenda Mallory

cc Khisa Lee

bcc

Subject Fw: NRDC v EPA (human research rule); CORRECTION to invitation for conference call

Can you please hold time in your calendars for a possible call with NRDC next Wednesday?

\*\*\*\*\*

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----- Forwarded by Angela Huskey/DC/USEPA/US on 07/08/2009 09:32 AM -----

From: "Greenberg, Alan (ENRD)" <AGreenbe@ENRD.USDOJ.GOV>  
To: Angela Huskey/DC/USEPA/US@EPA  
Date: 07/07/2009 04:36 PM  
Subject: FW: NRDC v EPA (human research rule); CORRECTION to invitation for conference call

---

FYI

**From:** Wall, Michael [mailto:mwall@nrdc.org]  
**Sent:** Tuesday, July 07, 2009 2:35 PM  
**To:** Greenberg, Alan (ENRD)  
**Subject:** RE: NRDC v EPA (human research rule); CORRECTION to invitation for conference call

We are not available July 14. We are likely available July 15 between 1 and 3 Eastern. I am confirming that and will let you know as soon as possible.

---

**From:** Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]  
**Sent:** Monday, July 06, 2009 8:59 AM  
**To:** Wall, Michael; jhasselman@earthjustice.org; vruiz@farmworkerjustice.org  
**Cc:** Huskey.Angela@epamail.epa.gov  
**Subject:** NRDC v EPA (human research rule); CORRECTION to invitation for conference call

Counsel:

Apologies, but EPA and I miscommunicated this morning. EPA would like to set up a conference call for July 14, but the ONLY time they have available on July 14 is from 3 pm to 4 pm eastern time. Does that time work for you? If not, EPA is available on Wednesday July 15 between 1 and 3 pm eastern time and at 4 pm eastern time. Please let me know which time is best for you.

Sorry for the confusion.

Alan

Angela Huskey/DC/USEPA/US

To Philip Ross

11/10/2009 09:01 AM

cc

bcc

Subject Re: Update Requested: Discuss human studies settlement

11.30-12 on Thursday.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
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Philip Ross

Update Requested: Discuss human studi...

11/09/2009 04:28:53 PM

**Update Requested: Discuss human studies settlement**

**Thu 11/12/2009 11:30 AM - 12:00 PM**

Location: Brenda's office

**Philip Ross Update Requested**

When is this meeting intended to be held? With the scheduling and then all the subsequent reschdulings, I'm not sure my calendar reflects the correct day and time?

Required:	Brenda Mallory/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA
Optional:	Robert Perlis/DC/USEPA/US@EPA

**Description**



**Angela Huskey/DC/USEPA/US**

To Scott Fulton

cc

01/19/2010 11:16 AM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Angela Huskey/DC/USEPA/US**

To Scott Fulton

cc

01/19/2010 11:37 AM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Angela Huskey/DC/USEPA/US**

To Scott Fulton

cc

01/21/2010 05:16 PM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Angela Huskey/DC/USEPA/US**

To Scott Fulton

cc

01/28/2010 11:56 AM

bcc

Subject Accepted: Discussion on Human Studies Settlement

Angela Huskey/DC/USEPA/US

To William Jordan, John Carley, Kelly Sherman

07/21/2009 11:18 AM

cc

bcc

Subject Petitioners' suggested language

***Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release***

Here's the email from the petitioners with their suggested language.

\*\*\*\*\*

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----- Forwarded by Angela Huskey/DC/USEPA/US on 07/21/2009 11:17 AM -----

From: "Wall, Michael" <mwall@nrhc.org>  
To: "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>  
Cc: Angela Huskey/DC/USEPA/US@EPA, <jhasselman@earthjustice.org>, <vrui@farmworkerjustice.org>  
Date: 07/20/2009 02:40 PM  
Subject: human testing rule - FRE 408 Communication

---

Settlement Communication \*\*\* Subject to Fed. R. Evid. 408

Alan:

We would like to discuss certain language on the call. Rather than redoing the whole redline /  
strikeout, I have pasted the new language below.

Section 26.1603(c)

Whether the proposed research presents an acceptable balance of risks and benefits. In making this determination for research intended to reduce the interspecies uncertainty factor in a pesticide risk assessment, the Administrator shall consider Recommendation 4-1 and the rationale of the National Research Council in developing that recommendation as contained in its report entitled Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues (2004).

Section 26.1705(c)

**Except as provided in Sec. 26.1706, EPA shall not rely on data from any research, unless EPA has adequate information to determine that the research was conducted in substantial compliance with**~~In determining whether research was conducted in substantial compliance with paragraph (b), EPA shall consider the extent to which any deficiencies in the ethical conduct of the study, including any deficiencies relative to the elements contained in section 26.1603(c)(4) through (10),~~ **did not** placed participants at increased risk of harm (based on knowledge available at the time the study was conducted), **and did not** ~~or impaired~~ their informed consent.

Angela Huskey/DC/USEPA/US

05/10/2009 09:12 PM

To William Jordan, John Carley  
cc Brenda Mallory, Keith Matthews  
bcc  
Subject Jim Jones meeting tomorrow

*Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release*

Bill/John,

I was just wondering if you had prepared/were preparing any paper for the Jim Jones meeting tomorrow. If so, would you mind sharing it with us? We'll do the same.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
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Washington, D.C. 20460

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Phone: (202) 564-2892  
Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To William Jordan, John Carley

cc Keith Matthews

bcc

04/30/2009 05:36 PM

Subject Call to discuss human studies rule

***Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release***

Bill/John,

Is there a time that would work for you either tomorrow or Monday morning to go over a few more things before the call with NRDC? In our conversation with Alan today, it seems that there are a few things we'd like clarified to ensure that we have all the details we need for the settlement negotiations.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
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Environmental Protection Agency  
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Washington, D.C. 20460

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Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To "Greenberg, Alan (ENRD)"

04/27/2009 02:48 PM

cc

bcc

Subject Call on May 4

***Attorney-Client Communication  
Attorney Work Product  
Pre-Decisional/Deliberative  
Privileged and Confidential--Do Not Release***

Alan,

Do we have a time set up for a call on May 4 with NRDC? I couldn't locate an email about it.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
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1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

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Phone: (202) 564-2892  
Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

07/27/2009 02:02 PM

To "Wall, Michael", Jan Hasselman, Virginia Ruiz

cc "Greenberg, Alan (ENRD)"

bcc

Subject FRE 408 Communication -- human subjects rule

Michael,

For our discussion this afternoon, here is EPA's response to your suggestions for 26.1705(c). We found your revisions to 26.1603(c) as contained in your email of 7/20/09 acceptable.

(c) Except as provided in Sec. 1706, EPA shall not rely on data from any research, unless EPA determines that the research was conducted in substantial compliance with one of the following:

(1) a proposal that was found to be acceptable relative to the elements contained in section 26.1603(c) and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA's evaluation of the proposal under section 26.1603(c), EPA shall not rely on that data.

(2) a proposal that would have been found acceptable relative to the elements contained in section 26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
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Angela Huskey/DC/USEPA/US

To "Wall, Michael"

cc

01/31/2011 01:45 PM

bcc

Subject Human subjects proposed rule publication date

Michael,

Just wanted to let you know that the proposed human subjects rule is scheduled for public display tomorrow and should publish in the Federal Register on Wednesday of this week.

Thanks,  
Angela

\*\*\*\*\*

Angela Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

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Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To "Wall, Michael"

05/14/2009 09:11 AM

cc "Greenberg, Alan (ENRD)"

bcc

Subject Today's call

Michael,

I apologize for the late notice, but due to some scheduling conflicts here and the fact that we are still working through and preparing a response to the points discussed on the last call with NRDC, EPA would like to reschedule our call for today to sometime next week. Also, we are working on some draft regulatory text that we would like to share with you before our next call, so we would prefer to schedule a time on next Wednesday or Thursday. Does that time work for you?

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To "Wall, Michael"

06/11/2009 09:33 AM

cc "Greenberg, Alan (ENRD)"

bcc Keith Matthews

Subject Question

Michael,

A question has come up here about what the petitioners have intended by one of the comments in the regulatory language, specifically, the new language in section 26.1705, and I was hoping you could clarify for us. The discussion we had on our last phone call indicated that petitioners' intent was to ensure that the Agency would not rely on any completed study results where the protocol did not meet the criteria in 26.1603. You mentioned an example where a protocol gets reviewed and is found to be not meeting one of the criteria, but the researcher conducts the study anyway and submits the results to EPA. And the language the petitioners added was intended to prohibit EPA from relying on such a study. This example indicates that the petitioners intend the 26.1603 criteria to apply to protocols.

The language, however, appears to be drafted more broadly. It appears to prohibit the Agency from relying on any completed study results where the completed study does not meet the criteria in 26.1603. An example could be where the protocol met the criteria in 26.1603 but then something happened during the study that made it not meet one of the criteria. Or another situation could be that the EPA reviews a protocol and considers that it meets all the criteria in 26.1603 but the HSRB wants the study to do more, which the researcher does not do. Do the petitioners intend to prohibit EPA from relying on those studies as well? Put another way, do the petitioners view the criteria in 26.1603 as equally applicable to protocols and completed studies or simply to protocols?

Thanks,  
Angela

\*\*\*\*\*

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Washington, D.C. 20460

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Phone: (202) 564-2892  
Fax: (202) 564-5644

Angela Huskey/DC/USEPA/US

To "Wall, Michael"

05/12/2009 12:02 PM

cc "Greenberg, Alan (ENRD)"

bcc

Subject RE: NRDC v EPA (human research rule)

Michael,

I appreciate the clarification, and I think it would be helpful to have an answer to both questions.

Thanks,  
Angela

\*\*\*\*\*

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Phone: (202) 564-2892  
Fax: (202) 564-5644

"Wall, Michael"

Alan: As we discussed, this is a very im...

05/11/2009 05:32:29 PM

From: "Wall, Michael" <mwall@nrdc.org>  
To: "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>  
Cc: Angela Huskey/DC/USEPA/US@EPA  
Date: 05/11/2009 05:32 PM  
Subject: RE: NRDC v EPA (human research rule)

Alan:

As we discussed, this is a very important issue for Petitioners. We do not yet have a formal further answer.

I would like to make sure I understand your present question: Does the question relate to EPA's application, in future decision making, of any newly adopted scientific standards to older studies? Or does the question relate to EPA revisiting pesticide decisions completed in the past (e.g., reassessment or reregistration decisions made after the appropriations rider was adopted, but before the date of any settlement) using newly adopted scientific standards?

Thanks,  
Michael

-----Original Message-----

From: Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]  
Sent: Monday, May 11, 2009 1:51 PM  
To: Wall, Michael  
Cc: Huskey.Angela@epamail.epa.gov  
Subject: NRDC v EPA (human research rule)

CONFIDENTIAL SETTLEMENT COMMUNICATION

Michael:

During our last phone conversation, EPA asked Petitioners about the relative importance of certain items to Petitioners in the settlement negotiations for this case. In particular, EPA asked NRDC to consider the relative importance of ensuring that the same scientific standards are applied to studies regardless of when the studies were conducted.

As EPA prepares for the follow-up call on Thursday, it would be helpful to know if Petitioners have considered further and have a response on this issue.

Thanks. Alan

Angela Huskey/DC/USEPA/US

02/10/2010 09:59 PM

To "Wall, Michael"

cc "Greenberg, Alan (ENRD)", "Jan Hasselman", "Virginia Ruiz"

bcc

Subject RE: Humane research rule

Michael,

Thank you for your response on this issue. I think it would be useful to set up a time to talk next week so that we can discuss this issue better. It's difficult to tell how close or far apart we are on this issue without further discussion. The best times for us would be Tuesday at 3 or 4 EST, Wednesday at 2 or 4 EST, or Thursday at 1 EST. If those times don't work, please let me know and I'll see what I can do about finding other available times on attendees' calendars.

For that meeting, it will be useful to get a sense about what types of studies the petitioners believe should be covered, both in subpart K (for third-party studies) and in subpart Q (studies the Agency wants to rely on). In particular, do the petitioners believe that studies involving substances that are sometimes used in pesticides (e.g., formaldehyde or an active ingredient that is used in prescription drugs) should always be subject to the rule, even if the intent of the study is only to test the substance when it might be used for non-pesticidal purposes? It will be helpful for us to walk through some examples to understand where everyone is on this issue.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
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1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

"Wall, Michael"

Alan:

02/10/2010 08:20:28 PM

From: "Wall, Michael" <mwall@nrdc.org>  
To: "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>  
Cc: Angela Huskey/DC/USEPA/US@EPA, "Virginia Ruiz" <vrui@farmworkerjustice.org>, "Jan Hasselman" <jhasselman@earthjustice.org>  
Date: 02/10/2010 08:20 PM  
Subject: RE: Humane research rule

Alan:

We have been unable timely to reach all of our clients, in part due to inclement weather on the East Coast. However, we would be willing to recommend to our clients that they accept EPA's proposed revision to the definition of pesticide (26.1102(k)). This change would limit the scope of the human testing rule to chemicals that EPA already regulates as pesticides and seems

calculated to satisfy the concerns identified below. The other changes suggested by EPA are not acceptable. There is no support in the text or history of the human testing legislation for the notion that Congress intended to exempt chemicals presently regulated by EPA as pesticides. Please let us know if you would like to set up a time to talk.

Michael

---

**From:** Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]

**Sent:** Monday, February 01, 2010 3:07 PM

**To:** Wall, Michael

**Cc:** huskey.angela@epa.gov

**Subject:** Humane research rule

CONFIDENTIAL SETTLEMENT COMMUNICATION

Michael:

As we discussed last week, EPA believes that the definition of pesticide in the July version of the regulatory language, which included substances that were ingredients in a pesticide as well as metabolites and degradates, has broad unintended consequences across the Agency. There are a number of substances that may be ingredients in a pesticide or may sometimes be pesticides themselves in some circumstances that might be swept into this rule, even though they were not pesticides in the human studies themselves. One example is a study in which exposure to formaldehyde is being tested with human subjects. Sometimes formaldehyde is used in pesticides, but it has a lot of other general chemical uses outside the pesticidal context. Studies involving the use of formaldehyde may or may not be using formaldehyde as a pesticide in the study and may or may not be testing the substance for pesticidal purposes. On the other hand, EPA wants to make sure that it is not narrowing the definition such that studies involving substances that are always pesticides are excluded somehow because of how the study is conducted (e.g., putting a pesticide in a capsule to test effects). EPA believes that the current draft refocuses the language on ensuring that the actual studies involving intentional exposure of humans to pesticides themselves are covered by the regulation without unnecessarily sweeping in other chemicals that have multiple uses.

I have attached a copy of EPA's red-lined version of Exhibit A to address EPA's concern in a manner that EPA believes will not adversely impact Petitioners' interests.

I will call you to discuss next steps.

Alan



Angela Huskey/DC/USEPA/US

To "Wall, Michael"

02/11/2010 09:36 PM

cc "Greenberg, Alan (ENRD)", "Jan Hasselman", "Virginia Ruiz"

bcc

Subject RE: Humane research rule

Michael,

Thanks for the update. We look forward to talking with you on Tuesday. If you are able to provide any response to my question or any clarity about the scope of studies to be covered by subparts K and Q (and to a lesser extent, M), that would be helpful. If not, we can just try to address those issues on Tuesday.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

"Wall, Michael"

Angela - We are trying to involve some...

02/11/2010 06:53:39 PM

From: "Wall, Michael" <mwall@nrhc.org>  
To: Angela Huskey/DC/USEPA/US@EPA  
Cc: "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>, "Jan Hasselman" <jhasselman@earthjustice.org>, "Virginia Ruiz" <vruiz@farmworkerjustice.org>  
Date: 02/11/2010 06:53 PM  
Subject: RE: Humane research rule

Angela -

We are trying to involve some of our clients, and have not yet heard back from them, but let's set aside 4:15 Eastern on Tuesday. (We are unavailable before then.) Thanks.

Michael

-----Original Message-----

From: Huskey.Angela@epamail.epa.gov  
[mailto:Huskey.Angela@epamail.epa.gov]  
Sent: Wednesday, February 10, 2010 7:00 PM  
To: Wall, Michael  
Cc: Greenberg, Alan (ENRD); Jan Hasselman; Virginia Ruiz  
Subject: RE: Humane research rule

Michael,

Thank you for your response on this issue. I think it would be useful to set up a time to talk next week so that we can discuss this issue

better. It's difficult to tell how close or far apart we are on this issue without further discussion. The best times for us would be Tuesday at 3 or 4 EST, Wednesday at 2 or 4 EST, or Thursday at 1 EST. If those times don't work, please let me know and I'll see what I can do about finding other available times on attendees' calendars.

For that meeting, it will be useful to get a sense about what types of studies the petitioners believe should be covered, both in subpart K (for third-party studies) and in subpart Q (studies the Agency wants to rely on). In particular, do the petitioners believe that studies involving substances that are sometimes used in pesticides (e.g., formaldehyde or an active ingredient that is used in prescription drugs) should always be subject to the rule, even if the intent of the study is only to test the substance when it might be used for non-pesticidal purposes? It will be helpful for us to walk through some examples to understand where everyone is on this issue.

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

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| From: |
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| "Wall, Michael" <mwall@nrdc.org>
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| To: |
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| "Greenberg, Alan (ENRD)" <Alan.Greenberg@usdoj.gov>
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| Cc: |
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>-----  
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|Angela Huskey/DC/USEPA/US@EPA, "Virginia Ruiz"  
<vrui@farmworkerjustice.org>, "Jan Hasselman"  
<jhasselman@earthjustice.org> |  
  
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|RE: Humane research rule  
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Alan:

We have been unable timely to reach all of our clients, in part due to inclement weather on the East Coast. However, we would be willing to recommend to our clients that they accept EPA's proposed revision to the definition of pesticide (26.1102(k)). This change would limit the scope of the human testing rule to chemicals that EPA already regulates as pesticides and seems calculated to satisfy the concerns identified below. The other changes suggested by EPA are not acceptable. There is no support in the text or history of the human testing legislation for the notion that Congress intended to exempt chemicals presently regulated by EPA as pesticides. Please let us know if you would like to set up a time to talk.

Michael

From: Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]  
Sent: Monday, February 01, 2010 3:07 PM  
To: Wall, Michael  
Cc: huskey.angela@epa.gov  
Subject: Humane research rule

CONFIDENTIAL SETTLEMENT COMMUNICATION

Michael:

As we discussed last week, EPA believes that the definition of pesticide in the July version of the regulatory language, which included substances that were ingredients in a pesticide as well as metabolites and degradates, has broad unintended consequences across the Agency. There are a number of substances that may be ingredients in a pesticide or may sometimes be pesticides themselves in some circumstances that might be swept into this rule, even though they were not pesticides in the human studies themselves. One example is a study in which exposure to formaldehyde is being tested with human subjects. Sometimes formaldehyde is used in pesticides, but it has a lot of other general chemical uses outside the pesticidal context. Studies involving the use of formaldehyde may or may not be using formaldehyde as a pesticide in the study and may or may not be testing the substance for pesticidal purposes. On the other hand, EPA wants to make sure that it is not narrowing the definition such that studies involving substances that are always pesticides are excluded somehow because of how the study is conducted (e.g., putting a pesticide in a capsule to test effects). EPA believes that the current draft refocuses the language on ensuring that the actual studies involving intentional exposure of humans to pesticides themselves are covered by the regulation without unnecessarily sweeping in other chemicals that have multiple uses.

I have attached a copy of EPA's red-lined version of Exhibit A to address EPA's concern in a manner that EPA believes will not adversely impact Petitioners' interests.

I will call you to discuss next steps.

Alan

Angela Huskey/DC/USEPA/US

To

cc

bcc

Subject Call w/Alan and Michael re human studies rule settlement

**Meeting**

Date 04/21/2009

Time 02:00:00 PM to 03:00:00 PM

Chair Angela Huskey

Invitees

Required

Optional

FYI

Location

---

Would 11:00 pacific time work for you? Would you like Angela to join the call?

Alan

-----Original Message-----

From: Wall, Michael [mailto:mwall@nrdc.org]  
Sent: Monday, April 20, 2009 10:35 PM  
To: Greenberg, Alan (ENRD)  
Cc: Huskey.Angela@epamail.epa.gov  
Subject: RE: NRDC v EPA (human research rule)

Alan:

I'd like to phone you tomorrow to discuss these matters. Let me know when would be a good time.

Best,  
Michael Wall

-----Original Message-----

From: Greenberg, Alan (ENRD) [mailto:Alan.Greenberg@usdoj.gov]  
Sent: Tuesday, April 14, 2009 12:12 PM  
To: Wall, Michael  
Cc: Huskey.Angela@epamail.epa.gov  
Subject: NRDC v EPA (human research rule)

Michael:

I know that you are out of the office this week, but we were hoping to get an estimate of when petitioners will be able to provide EPA with the list of priorities that we discussed during our call on April 2.  
Thanks.

Alan

Cc: Angela Huskey



**Angela Huskey/DC/USEPA/US**

To

cc

10/14/2009 04:09 PM

bcc

Subject Discuss human studies rule settlement agreement; impact on timelines for DDVP, aldicarb, and amitraz

**Meeting**

Date 10/19/2009

Time 12:00:00 PM to 01:00:00 PM

Chair Angela Huskey

Invitees

Required Christine Olinger; Danette Drew; Jack Arthur; James Parker; John Carley;  
Joy Schnackenbeck; Keith Matthews; Kelly Sherman; Laura Parsons;  
Michael Metzger; Philip Ross; Ray Kent; William Jordan

Optional Brenda Mallory; Jonathan Fleuchaus

FYI

Location If you're not in Ariel Rios, you can use  
the following conference line:

(b) (6)

A large black rectangular redaction box covers the content of the conference line.

**Angela Huskey/DC/USEPA/US**

To

cc

11/10/2009 02:37 PM

bcc

Subject Discuss human studies settlement

**Meeting**

Date 11/12/2009

Time 11:30:00 AM to 12:00:00 PM

Chair Angela Huskey

Invitees

Required Brenda Mallory; Jonathan Fleuchaus; Keith Matthews; Philip Ross

Optional Robert Perlis

FYI

Location Brenda's office

**Angela Huskey/DC/USEPA/US**

To

02/16/2010 01:30 PM

cc

bcc

Subject Discuss human studies settlement

**Meeting**

Date 02/17/2010

Time 11:30:00 AM to 12:30:00 PM

Chair Angela Huskey

Invitees

Required Brenda Mallory; Charlotte Bertrand; Lesley Schaaff

Optional

FYI

Location

**Angela Huskey/DC/USEPA/US**

To

cc

10/17/2006 01:41 PM

bcc

Subject Discuss response for Human Studies litigation

**Meeting**

Date 10/23/2006

Time 02:00:00 PM to 03:00:00 PM

Chair Angela Huskey

Invitees

Required John Carley; Keith Matthews; William Jordan

Optional Lee Tyner; Philip Ross

FYI

Location

Since we're likely to have more people attending from OGC now, I've gone ahead and set up a conference room over here.

Angela Huskey/DC/USEPA/US

To

cc

bcc

Subject Fw: Human Studies Settlement - Conference Call

### Meeting

Date 05/27/2009

Time 03:30:00 PM to 04:00:00 PM

Chair Angela Huskey

Invitees

Required

Optional

FYI

Location

---

Can we get together at 3:30 to confer on today's call? It looks like 7500 is available.

----- Forwarded by Keith Matthews/DC/USEPA/US on 05/27/2009 01:54 PM -----

### Human Studies Settlement - Conference Call

Wed 05/27/2009 4:00 PM - 5:00 PM

Attendance is for Keith Matthews

Chair: Brenda Mallory/DC/USEPA/US

Sent By: Khisa Lee/DC/USEPA/US

Rooms: Conf Rm 7500/DC-Ariel Rios-OGC@EPA

This entry has an alarm. The alarm will go off 30 minutes before the entry starts.

Required:

Angela Huskey/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA

Description

---

## Personal Notes

---

**Angela Huskey/DC/USEPA/US**

To

07/20/2006 11:18 AM

cc

bcc

Subject Human Studies Litigation

**Meeting**

Date 07/20/2006

Time 03:30:00 PM to 04:00:00 PM

Chair Angela Huskey

Invitees

Required Kevin Minoli

Optional

FYI

Location

**Angela Huskey/DC/USEPA/US**

To

08/09/2006 02:25 PM

cc

bcc

Subject Human Studies Litigation

**Meeting**

Date 08/09/2006

Time 04:00:00 PM to 04:30:00 PM

Chair Angela Huskey

Invitees

Required Keith Matthews

Optional

FYI

Location

**Avi Garbow/DC/USEPA/US**

11/16/2009 01:43 PM

To Brenda Mallory

cc

bcc

Subject human studies

Brenda,

I've got a meeting at 3 Wed. re: human studies litigation. This may be a briefing that your shop set up for me (my calendar entry doesn't tell me who is involved). I now have a conflict then. Can we either move that briefing to 3 tomorrow (Tues.) or else to 2 on Wed.?

Avi Garbow  
Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-1917

Avi Garbow/DC/USEPA/US  
04/09/2010 03:06 PM

To Brenda Mallory  
cc Monique Patrick  
bcc  
Subject Re: Human subjects settlement

Thanks  
Brenda Mallory

----- Original Message -----

**From:** Brenda Mallory  
**Sent:** 04/09/2010 03:01 PM EDT  
**To:** Avi Garbow  
**Cc:** Monique Patrick  
**Subject:** Fw: Human subjects settlement

You may want to come to this as well. Thanks.

Brenda Mallory  
Principal Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-8064 (telephone)  
(202) 564- 1777 (fax)  
mallory.brenda@epa.gov

----- Forwarded by Brenda Mallory/DC/USEPA/US on 04/09/2010 03:00 PM -----

### Human subjects settlement

**Mon 04/12/2010 9:15 AM - 9:30 AM**

Attendance is for Brenda Mallory

Chair: **Lisa Heinzerling/DC/USEPA/US**  
Location: ARN 3513

---

Required:	Bob Sussman/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Scott Fulton/DC/USEPA/US@EPA
Optional:	Bob Perciasepe/DC/USEPA/US@EPA

Description

---

## Personal Notes

---

**Avi Garbow/DC/USEPA/US**

02/25/2010 05:49 PM

To Carla Veney

cc Brenda Mallory

bcc

Subject Time with Scott tomorrow

Carla,

Brenda and I would like to get some additional time with Scott tomorrow on the matter of the Human Studies settlement (just mentioned this to Scott this evening). I know he's pretty booked, but any chance we could enlarge the meeting we've already got scheduled with him in the afternoon by 15 minutes or so? Thanks.

Avi Garbow  
Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-1917

Avi Garbow/DC/USEPA/US  
03/11/2010 07:07 PM

To Lisa Heinzerling, Brenda Mallory  
cc "Nicole Owens"  
bcc  
Subject Re: Human subjects settlement

Thanks lisa. We can transmit.

Avi  
Lisa Heinzerling

----- Original Message -----

**From:** Lisa Heinzerling  
**Sent:** 03/11/2010 07:04 PM EST  
**To:** Avi Garbow; Brenda Mallory  
**Cc:** "Nicole Owens" <owens.nicole@epa.gov>  
**Subject:** Human subjects settlement

OIRA says we may not transmit this through ROCIS under EO, must transmit through OMB OGC. They say two weeks or less.

Let us know if you need anything. I take it you'll transmit to OMB OGC?

Thanks.

**Avi Garbow/DC/USEPA/US**

01/19/2010 11:10 AM

To Scott Fulton

cc

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Avi Garbow/DC/USEPA/US**

01/19/2010 11:48 AM

To Scott Fulton

cc

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Avi Garbow/DC/USEPA/US**

01/21/2010 05:14 PM

To Scott Fulton

cc

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Avi Garbow/DC/USEPA/US**

01/29/2010 08:14 AM

To Scott Fulton

cc

bcc

Subject Accepted: Discussion on Human Studies Settlement

Bob Sussman/DC/USEPA/US

03/04/2010 02:37 PM

To Paul Anastas

cc

bcc

Subject Re: Human Studies

Great.

Paul Anastas

----- Original Message -----

**From:** Paul Anastas

**Sent:** 03/04/2010 12:14 PM EST

**To:** Bob Sussman

**Cc:** Bob Perciasepe; Lisa Heinzerling; Richard Windsor; Scott Fulton

**Subject:** Re: Human Studies

Bob:

yes, I view this as an important issue and will be moving ahead with it. It is not an isolated discreet issue and so I am taking the time needed to understand the cross-program activities and implications. While the overall strategy will not be developed immediately due to its complexity, we will be acting quickly to begin to address this issue.

PTA

Bob Sussman

[Paul -- thanks for the time you took to w...](#)

03/04/2010 10:05:43 AM

From: Bob Sussman/DC/USEPA/US

To: Paul Anastas/DC/USEPA/US@EPA

Cc: Richard Windsor/DC/USEPA/US@EPA, Bob Perciasepe/DC/USEPA/US@EPA, Scott Fulton/DC/USEPA/US@EPA, Lisa Heinzerling/DC/USEPA/US@EPA

Date: 03/04/2010 10:05 AM

Subject: Human Studies

Paul -- thanks for the time you took to work through the settlement language for the human studies litigation. And also thanks for being accommodating and allowing the settlement to move forward. As I've indicated to the Administrator and we've discussed, the larger challenge is to make sure that our policies on human subjects testing are well-aligned and consistent across the agency. This is where you can play a critical role in your Science Advisor capacity. I hope you'll pick up this challenge and bring some recommendations to the Administrator. Let us know how we can help. Thanks again!

Robert M. Sussman

Senior Policy Counsel to the Administrator

Office of the Administrator

US Environmental Protection Agency

**Bob Sussman/DC/USEPA/US**

03/04/2010 10:05 AM

To Paul Anastas

cc Richard Windsor, Bob Perciasepe, Scott Fulton, Lisa  
Heinzerling

bcc

Subject Human Studies

Paul -- thanks for the time you took to work through the settlement language for the human studies litigation. And also thanks for being accommodating and allowing the settlement to move forward. As I've indicated to the Administrator and we've discussed, the larger challenge is to make sure that our policies on human subjects testing are well-aligned and consistent across the agency. This is where you can play a critical role in your Science Advisor capacity. I hope you'll pick up this challenge and bring some recommendations to the Administrator. Let us know how we can help. Thanks again!

Robert M. Sussman  
Senior Policy Counsel to the Administrator  
Office of the Administrator  
US Environmental Protection Agency

**Brenda Mallory/DC/USEPA/US**

To Alecia Allston

11/13/2009 10:52 AM

cc

bcc

Subject Re: Meeting with Avi

great. thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Alecia Allston

[I moved it to 3pm. That's all he has left t...](#)

11/13/2009 09:23:00 AM

From: Alecia Allston/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/13/2009 09:23 AM  
Subject: Re: Meeting with Avi

---

I moved it to 3pm. That's all he has left that day.

Alecia Allston  
Staff Assistant  
Deputy Administrator's office  
202-564-0880

Brenda Mallory

[Alecia - I have a conflict at that time tha...](#)

11/13/2009 09:11:43 AM

From: Brenda Mallory/DC/USEPA/US  
To: Alecia Allston/DC/USEPA/US@EPA  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/13/2009 09:11 AM  
Subject: Re: Meeting with Avi

---

Alecia - I have a conflict at that time that I can not move. Can you find another time. My calendar is up to date. I am free between 11 and 1 and I could also miss the Associates meeting at 3 if I had to. Thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Alecia Allston

[done Alecia Allston](#)

11/13/2009 09:06:47 AM

From: Alecia Allston/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/13/2009 09:06 AM  
Subject: Re: Meeting with Avi

---

done

Alecia Allston  
Staff Assistant  
Deputy Administrator's office  
202-564-0880

Brenda Mallory    Alecia - I spoke to Avi about getting a m...    11/12/2009 09:07:11 PM

From: Brenda Mallory/DC/USEPA/US  
To: "Alecia Allston" <Allston.Alecia@epamail.epa.gov>  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/12/2009 09:07 PM  
Subject: Meeting with Avi

---

Alecia - I spoke to Avi about getting a meeting on his calendar on the Human Studies litigation. Originally, it was going to be a Background briefing but we now need his input on an issue. Can you schedule something for Wednesday or later with Angela Huskey, Phil Ross, Keith Matthews, Jon Fleuchaus, and me. Thanks.

-----  
Sent by EPA Wireless E-Mail Services

**Brenda Mallory/DC/USEPA/US**

11/13/2009 09:11 AM

To Alecia Allston

cc "Robin Spriggs"

bcc

Subject Re: Meeting with Avi

Alecia - I have a conflict at that time that I can not move. Can you find another time. My calendar is up to date. I am free between 11 and 1 and I could also miss the Associates meeting at 3 if I had to. Thanks.

Brenda Mallory

Associate General Counsel, Pesticide and Toxic Substances Law Office

U.S. Environmental Protection Agency

(202) 564-0633 (telephone)

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mallory.brenda@epa.gov

Alecia Allston

done Alecia Allston

11/13/2009 09:06:47 AM

From: Alecia Allston/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/13/2009 09:06 AM  
Subject: Re: Meeting with Avi

---

done

Alecia Allston

Staff Assistant

Deputy Administrator's office

202-564-0880

Brenda Mallory

Alecia - I spoke to Avi about getting a m...

11/12/2009 09:07:11 PM

From: Brenda Mallory/DC/USEPA/US  
To: "Alecia Allston" <Allston.Alecia@epamail.epa.gov>  
Cc: "Robin Spriggs" <spriggs.robin@epa.gov>  
Date: 11/12/2009 09:07 PM  
Subject: Meeting with Avi

---

Alecia - I spoke to Avi about getting a meeting on his calendar on the Human Studies litigation. Originally, it was going to be a Background briefing but we now need his input on an issue. Can you schedule something for Wednesday or later with Angela Huskey, Phil Ross, Keith Matthews, Jon Fleuchaus, and me. Thanks.

-----  
Sent by EPA Wireless E-Mail Services

**Brenda Mallory/DC/USEPA/US**

To Angela Huskey

cc

11/09/2009 05:10 PM

bcc

Subject Accepted: Discuss human studies settlement

**Brenda Mallory/DC/USEPA/US**

To Angela Huskey

cc

02/16/2010 01:33 PM

bcc

Subject Accepted: Discuss human studies settlement

**Brenda Mallory/DC/USEPA/US**

To Angela Huskey

cc

02/17/2010 10:47 AM

bcc

Subject Accepted: Discuss human studies settlement

**Brenda Mallory/DC/USEPA/US**

To Angela Huskey

cc

11/09/2009 02:44 PM

bcc

Subject Declined: Discuss human studies settlement

**Brenda Mallory/DC/USEPA/US**

To Angela Huskey

cc

01/06/2010 02:52 PM

bcc

Subject What's happening on the Human Studies case? nm

Brenda Mallory

Associate General Counsel, Pesticide and Toxic Substances Law Office

U.S. Environmental Protection Agency

(202) 564-0633 (telephone)

(202) 564- 5644 (fax)

mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

11/17/2009 12:00 PM

To Angela Huskey

cc Jonathan Fleuchaus, Keith Matthews, Robin Spriggs

bcc

Subject Re: HEADS UP - Human Studies Litigation Mtg.

Great. Thanks, Angela!

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Angela Huskey | I can be available at that time. \*\*\*\*\*... 11/17/2009 11:32:30 AM

From: Angela Huskey/DC/USEPA/US  
To: Robin Spriggs/DC/USEPA/US@EPA  
Cc: Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 11/17/2009 11:32 AM  
Subject: Re: HEADS UP - Human Studies Litigation Mtg.

I can be available at that time.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

Robin Spriggs | Avi has another meeting at OMB and w... 11/17/2009 10:50:20 AM

From: Robin Spriggs/DC/USEPA/US  
To: Angela Huskey/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 11/17/2009 10:50 AM  
Subject: HEADS UP - Human Studies Litigation Mtg.

Avi has another meeting at OMB and would like to start the Human Studies meeting a little later would 4:30 today work for you guys?

**Brenda Mallory/DC/USEPA/US**

11/16/2009 01:51 PM

To: Avi Garbow

cc: Angela Huskey, Keith Matthews, Robert Perlis, Khisa Lee,  
Robin Spriggs

bcc:

Subject: Re: human studies

Yes, this is our meeting. Let me consult with the team. We do need to talk to you this week so we'll see what we can do with other meetings we have. If it is tomorrow, we won't be able to get materials to you today. I'll circle back.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Avi Garbow

[Brenda, I've got a meeting at 3 Wed. re...](#)

11/16/2009 01:43:06 PM

From: Avi Garbow/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Date: 11/16/2009 01:43 PM  
Subject: human studies

Brenda,

I've got a meeting at 3 Wed. re: human studies litigation. This may be a briefing that your shop set up for me (my calendar entry doesn't tell me who is involved). I now have a conflict then. Can we either move that briefing to 3 tomorrow (Tues.) or else to 2 on Wed.?

Avi Garbow  
Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-1917

**Brenda Mallory/DC/USEPA/US**

To Carla Veney

01/28/2010 11:14 AM

cc

bcc

Subject Human Studies settlement

We have some breaking developments in the Human Studies settlement that I need to raise to his attention. Is he back in town tomorrow? Can we get 15 - 30 minutes with him? We are preparing a note updating him but ideally I would like to speak to him (Note - we're still waiting for some feedback from Steve Owens so probably we won't be ready to talk to him until tomorrow.) Let me know. Thanks.

Brenda Mallory

Associate General Counsel, Pesticide and Toxic Substances Law Office

U.S. Environmental Protection Agency

(202) 564-0633 (telephone)

(202) 564- 5644 (fax)

mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

To Carla Veney

01/28/2010 11:47 AM

cc

bcc

Subject Re: Human Studies settlement

Add Bob Perlis and Keith Matthews as optional. It will probably just be the two of us. Thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Carla Veney OK, is it just the two of you? Carla Ven... 01/28/2010 11:45:42 AM

From: Carla Veney/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Cc: Angela Huskey/DC/USEPA/US@EPA  
Date: 01/28/2010 11:45 AM  
Subject: Re: Human Studies settlement

OK, is it just the two of you?

Carla Veney  
Program Specialist  
Office of the General Counsel  
Environmental Protection Agency  
Main: 202-564-8040  
Direct: 202-564-1619  
Fax: 202-564-1778

Brenda Mallory Great! We'll take it. We may need to p... 01/28/2010 11:44:01 AM

From: Brenda Mallory/DC/USEPA/US  
To: Carla Veney/DC/USEPA/US@EPA  
Cc: Angela Huskey/DC/USEPA/US@EPA  
Date: 01/28/2010 11:44 AM  
Subject: Re: Human Studies settlement

Great! We'll take it. We may need to patch in Angela by phone. Thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Carla Veney Right now, I can give you 12-12:30. wo... 01/28/2010 11:34:47 AM

From: Carla Veney/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Date: 01/28/2010 11:34 AM

Subject: Re: Human Studies settlement

---

Right now, I can give you 12-12:30. work?

Carla Veney  
Program Specialist  
Office of the General Counsel  
Environmental Protection Agency  
Main: 202-564-8040  
Direct: 202-564-1619  
Fax: 202-564-1778

---

Brenda Mallory	We have some breaking developments...	01/28/2010 11:14:31 AM
----------------	---------------------------------------	------------------------

From:	Brenda Mallory/DC/USEPA/US
To:	Carla Veney/DC/USEPA/US@EPA
Date:	01/28/2010 11:14 AM
Subject:	Human Studies settlement

---

We have some breaking developments in the Human Studies settlement that I need to raise to his attention. Is he back in town tomorrow? Can we get 15 - 30 minutes with him? We are preparing a note updating him but ideally I would like to speak to him (Note - we're still waiting for some feedback from Steve Owens so probably we won't be ready to talk to him until tomorrow.) Let me know. Thanks.

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U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

To Carla Veney

01/28/2010 11:44 AM

cc Angela Huskey

bcc

Subject Re: Human Studies settlement

Great! We'll take it. We may need to patch in Angela by phone. Thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Carla Veney

Right now, I can give you 12-12:30. wo...

01/28/2010 11:34:47 AM

From: Carla Veney/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Date: 01/28/2010 11:34 AM  
Subject: Re: Human Studies settlement

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Carla Veney  
Program Specialist  
Office of the General Counsel  
Environmental Protection Agency  
Main: 202-564-8040  
Direct: 202-564-1619  
Fax: 202-564-1778

Brenda Mallory

We have some breaking developments...

01/28/2010 11:14:31 AM

From: Brenda Mallory/DC/USEPA/US  
To: Carla Veney/DC/USEPA/US@EPA  
Date: 01/28/2010 11:14 AM  
Subject: Human Studies settlement

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U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

10/27/2008 11:25 AM

To Jonathan Fleuchaus

cc Robert Perlis

bcc

Subject Stipulation withdrawing Petition

I have a signed order from the Second Circuit on a stipulation entered by Aaron Colangelo and Kent Hanson withdrawing the petition for review until there is a decision in another case (which I assume is the Human Studies case). If you need a copy, feel free to collect from my box. I am going to give to Val to file. THanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

To Keith Matthews, Angela Huskey

cc

03/30/2009 05:12 PM

bcc

Subject Human Studies settlement

I told Jim that the first session would just include lawyers. He thought that was a good idea.

Brenda Mallory

Associate General Counsel, Pesticide and Toxic Substances Law Office

U.S. Environmental Protection Agency

(202) 564-0633 (telephone)

(202) 564- 5644 (fax)

mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

03/02/2006 01:19 PM

To Keith Matthews

cc Brian Grant, OGC PTSLO, Philip Ross

bcc

Subject Re: Fw: 3rd party Rule

I received a copy of the 9th Circuit Petition and it is in the Circuit Court. There may be something in District Court as well but this definitely said Circuit Court.


Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov  
Keith Matthews/DC/USEPA/US

**Keith  
Matthews/DC/USEPA/US**

03/02/2006 01:08 PM

To Philip Ross/DC/USEPA/US@EPA

cc Brian Grant/DC/USEPA/US@EPA, OGC PTSLO

Subject Re: Fw: 3rd party Rule 


We have recent intelligence indicating that the 9th Circuit suit is in District Court. Mary Grady is still attempting to run down a complaint for us.  
Philip Ross/DC/USEPA/US

**Philip Ross/DC/USEPA/US**

03/02/2006 12:56 PM

To Brian Grant/DC/USEPA/US@EPA

cc OGC PTSLO

Subject Re: Fw: 3rd party Rule 

Attorney Client Communication  
Attorney Work Product  
Deliberative  
Privileged and Confidential  
Do Not Release

Could the inquiry possibly relate to the Human Subjects final rule which covers, among other things, third-party human subject studies?

If so, the answer is yes. Keith characterized the pending round of litigation in the following manner: "NRDC and other environmental organizations are purported to have filed petitions for review of EPA's final human testing rule in both the 2d Second Circuit and the 9th Circuit (NRDC has shared a copy of its 2d Circuit petition; the petition in the 9th Circuit has been reported in the media)."

Philip J. Ross  
United States Environmental Protection Agency  
Office of General Counsel

Pesticides and Toxic Substances Law Office  
202-564-5637

Brian Grant/DC/USEPA/US

**Brian Grant/DC/USEPA/US**

03/02/2006 12:14 PM

To OGC PTSLO

cc

Subject Fw: 3rd party Rule

maybe i should, but i have no idea what the third party rule is. if you know, could you please let me know so i can get back to susie? thanks.

Brian Grant  
Office of General Counsel (2333 A)  
U.S. EPA  
phone: (202) 564-5503  
fax: (202) 564-5644

----- Forwarded by Brian Grant/DC/USEPA/US on 03/02/2006 12:13 PM -----

**Susan Hazen/DC/USEPA/US**

03/02/2006 08:58 AM

To Brian Grant/DC/USEPA/US@EPA

cc

Subject 3rd party Rule

I have been asked if we have been sued regarding the "3rd party Rule"

Any info?

Susan B. Hazen,  
Acting Assistant Administrator  
Office of Prevention, Pesticides and Toxic Substances  
(Phone) 202-564-2910 (fax) 202-564-0512

**Brenda Mallory/DC/USEPA/US**

11/17/2009 10:54 AM

To Keith Matthews

cc Angela Huskey, Jonathan Fleuchaus, Robin Spriggs

bcc

Subject Re: HEADS UP - Human Studies Litigation Mtg.

Thanks. I'm checking with Angela. SHE's more critical for this meeting and it generally is not good for her. I told Robin we'd circle back. Thanks.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Keith Matthews

This is actually better for me. ----- Or...

11/17/2009 10:52:42 AM

From: Keith Matthews/DC/USEPA/US  
To: Robin Spriggs/DC/USEPA/US@EPA, Angela Huskey/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA  
Date: 11/17/2009 10:52 AM  
Subject: Re: HEADS UP - Human Studies Litigation Mtg.

---

This is actually better for me.

Robin Spriggs

----- Original Message -----

**From:** Robin Spriggs

**Sent:** 11/17/2009 10:50 AM EST

**To:** Angela Huskey; Brenda Mallory; Jonathan Fleuchaus; Keith Matthews

**Subject:** HEADS UP - Human Studies Litigation Mtg.

Avi has another meeting at OMB and would like to start the Human Studies meeting a little later would 4:30 today work for you guys?

**Brenda Mallory/DC/USEPA/US**

To Scott Fulton

cc

01/19/2010 11:49 AM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Brenda Mallory/DC/USEPA/US**

To Scott Fulton

cc

01/21/2010 05:14 PM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Brenda Mallory/DC/USEPA/US**

To Scott Fulton

cc

01/28/2010 12:15 PM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Brenda Mallory/DC/USEPA/US**

To "Aitken, Steven D."

03/26/2010 05:11 PM

cc

bcc

Subject Re: EPA Settlement Agreement in Human Studies litigation - status?

Steve - Are there still going to be follow up questions?

Brenda Mallory  
Principal Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-8064 (telephone)  
(202) 564- 1777 (fax)  
mallory.brenda@epa.gov

"Aitken, Steven D."

[Brenda -- Thanks. The Friday call...](#)

03/25/2010 08:04:43 AM

From: "Aitken, Steven D." <Steven\_D.\_Aitken@omb.eop.gov>  
To: Brenda Mallory/DC/USEPA/US@EPA  
Date: 03/25/2010 08:04 AM  
Subject: Re: EPA Settlement Agreement in Human Studies litigation - status?

---

Brenda -- Thanks. The Friday call was very productive (thank you again), and I think that we will have a few follow-up questions today.

----- Original Message -----

From: Mallory.Brenda@epamail.epa.gov <Mallory.Brenda@epamail.epa.gov>  
To: Aitken, Steven D.  
Sent: Thu Mar 25 07:05:48 2010  
Subject: RE: EPA Settlement Agreement in Human Studies litigation - status?

Hey, Steve. Just checking in on how the review of the Human Studies Settlement is going? Are we still on track for OMB completing its review on Monday? Let me know. Thanks.

Brenda Mallory  
Principal Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-8064 (telephone)  
(202) 564- 1777 (fax)  
mallory.brenda@epa.gov

**Brenda Mallory/DC/USEPA/US**

To "Alecia Allston"

cc "Robin Spriggs"

bcc

11/12/2009 09:07 PM

Subject Meeting with Avi

Alecia - I spoke to Avi about getting a meeting on his calendar on the Human Studies litigation. Originally, it was going to be a Background briefing but we now need his input on an issue. Can you schedule something for Wednesday or later with Angela Huskey, Phil Ross, Keith Matthews, Jon Fleuchaus, and me. Thanks.

-----

Sent by EPA Wireless E-Mail Services

**Brenda Mallory/DC/USEPA/US**

02/16/2010 06:54 PM

To "Carla Veney"

cc "Brian Grant", "Christopher Kaczmarek", "Robert Perlis"

bcc

Subject Reg Review

Carla - I have a 3:00 meeting with Bob Sussman on the Human studies litigation that conflicts with PTSLO's Reg Review on Thursday. Avi has also been invited to this meeting. Is it possible to move the Reg Review to another time on Thursday? If not, don't worry about it. The Reg Review can go forward with the Assistants. Thanks.

-----

Sent by EPA Wireless E-Mail Services

**Brian Grant/DC/USEPA/US**

05/23/2007 05:20 PM

To Brenda Mallory

cc

bcc

Subject Accepted: Motion to Join EPA in Human Studies Case

**Byron Brown/DC/USEPA/US**

02/13/2009 01:03 PM

To Brenda Mallory

cc Keith Matthews

bcc

Subject Re: Human Studies Litigation

He works in OCIR on ORD issues. He said there is a briefing for Congressional staff at the end of the month to discuss the human studies program. He is looking for background on the litigation.

Brenda Mallory

[Who is this person?](#) Brenda Mallory

02/13/2009 12:52:19 PM

From: Brenda Mallory/DC/USEPA/US  
To: Byron Brown/DC/USEPA/US@EPA  
Cc: Keith Matthews/DC/USEPA/US@EPA  
Date: 02/13/2009 12:52 PM  
Subject: Re: Human Studies Litigation

---

Who is this person?

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Byron Brown

[David, OGC's Pesticides and Toxic Su...](#)

02/13/2009 12:32:38 PM

From: Byron Brown/DC/USEPA/US  
To: David Piantanida/DC/USEPA/US@EPA  
Cc: Brenda Mallory/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 02/13/2009 12:32 PM  
Subject: Human Studies Litigation

---

David, OGC's Pesticides and Toxic Substances Law Office handles this issue. I've copied Brenda Mallory, who heads the law office, and Keith Matthews, who has worked on the litigation. They should be able to help assist you with preparing for the Congressional briefing.

**Byron Brown/DC/USEPA/US**

02/13/2009 12:32 PM

To David Piantanida

cc Brenda Mallory, Keith Matthews

bcc

Subject Human Studies Litigation

David, OGC's Pesticides and Toxic Substances Law Office handles this issue. I've copied Brenda Mallory, who heads the law office, and Keith Matthews, who has worked on the litigation. They should be able to help assist you with preparing for the Congressional briefing.

**Byron Brown/DC/USEPA/US**

11/13/2009 03:03 PM

To "Robert Perlis", "Angela Huskey", "Jennifer Wills"

cc

bcc

Subject Human studies

Do you know how long the stay is in place? When do we need to get the settlement settled? Thanks.

-----

Sent by EPA Wireless E-Mail Services

**Scott Fulton/DC/USEPA/US**  
Sent by: Carla Veney

01/21/2010 05:02 PM

To Angela Huskey, Avi Garbow, Brenda Mallory, Chris  
Kaczmarek, Jonathan Fleuchaus, Keith Matthews, Robert  
Perlis

cc

bcc

Subject Rescheduled: Discussion on Human Studies Settlement (Jan  
22 09:30 AM EST in 4045)

**Scott Fulton/DC/USEPA/US**  
Sent by: Carla Veney

01/19/2010 11:20 AM

To Angela Huskey, Avi Garbow, Brenda Mallory, Chris  
Kaczmarek, Jonathan Fleuchaus, Keith Matthews, Robert  
Perlis

cc

bcc

Subject Rescheduled: Discussion on Human Studies Settlement (Jan  
22 10:45 AM EST in 4045)

**Scott Fulton/DC/USEPA/US**  
Sent by: Carla Veney

01/29/2010 08:01 AM

To Angela Huskey, Brenda Mallory

cc Keith Matthews, Robert Perlis

bcc

Subject Information Update - Location has changed: Discussion on  
Human Studies Settlement

**Carla Veney/DC/USEPA/US**

04/16/2010 03:02 PM

To Brenda Mallory, Leslye Fraser

cc

bcc

Subject FDA is asking for more information regarding the human studies case

I just received a call from them. Is there something I can send to folks today to prepare them for the meeting? It looks like the meeting will probably be on Tuesday at 10:00. Thanks!

Carla Veney  
Program Specialist  
Office of the General Counsel  
Environmental Protection Agency  
Main: 202-564-8040  
Direct: 202-564-1619  
Fax: 202-564-1778

**Scott Fulton/DC/USEPA/US**  
Sent by: Carla Veney

To

cc

01/19/2010 10:19 AM

bcc

Subject Discussion on Human Studies Settlement

### **Meeting**

Date 01/22/2010

Time 09:30:00 AM to 10:15:00 AM

Chair Scott Fulton

Invitees

Required Angela Huskey; Avi Garbow; Brenda Mallory; Chris Kaczmarek; Jonathan  
Fleuchaus; Keith Matthews; Robert Perlis

Optional

FYI

Location 4045

**Charlotte**  
**Bertrand/DC/USEPA/US**  
02/16/2010 02:11 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss human studies settlement

**Charlotte**  
**Bertrand/DC/USEPA/US**  
02/17/2010 10:47 AM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss human studies settlement

**Charlotte**  
**Bertrand/DC/USEPA/US**  
02/17/2010 10:39 AM

To Angela Huskey  
cc  
bcc  
Subject Countered: Discuss human studies settlement

**Chris**  
**Kaczmarek/DC/USEPA/US**  
01/19/2010 11:16 AM

To Scott Fulton  
cc  
bcc  
Subject Accepted: Discussion on Human Studies Settlement

**Chris**  
**Kaczmarek/DC/USEPA/US**  
01/19/2010 11:24 AM

To Scott Fulton  
cc  
bcc  
Subject Accepted: Discussion on Human Studies Settlement

**Chris**  
**Kaczmarek/DC/USEPA/US**  
01/25/2010 04:21 PM

To Scott Fulton  
cc  
bcc  
Subject Declined: Discussion on Human Studies Settlement

David  
Piantanida/DC/USEPA/US  
09/03/2009 04:37 PM

To Brenda Mallory, Keith Matthews  
cc Byron Brown, Sven-Erik Kaiser  
bcc  
Subject Re: Human Studies Litigation

Brenda and Keith,

I am the Congressional liaison for ORD and they are looking to get started with the "new and improved" version of the observational studies initiative. We have briefed EPW on this issue and ORD is poised to publish an RFA for children's exposure research. The other piece of this puzzle is the litigation/legal issue that I know you have been working on for years. Are you able to share where the litigation stands?

Thanks,

David Piantanida, (202) 564-8318  
U.S. Environmental Protection Agency  
OCIR / Office of Congressional Affairs  
Piantanida.David@epa.gov

Byron Brown	David, OGC's Pesticides and Toxic Su...	02/13/2009 12:32:43 PM
-------------	---	------------------------

From: Byron Brown/DC/USEPA/US  
To: David Piantanida/DC/USEPA/US@EPA  
Cc: Brenda Mallory/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 02/13/2009 12:32 PM  
Subject: Human Studies Litigation

---

David, OGC's Pesticides and Toxic Substances Law Office handles this issue. I've copied Brenda Mallory, who heads the law office, and Keith Matthews, who has worked on the litigation. They should be able to help assist you with preparing for the Congressional briefing.

**Debbie  
Edwards/DC/USEPA/US**

07/07/2009 02:50 PM

To William Jordan, Margie Fehrenbach, Debby Sisco

cc Steven Bradbury

bcc

Subject Fw: another items for Steve O

FYI.

----- Forwarded by Debbie Edwards/DC/USEPA/US on 07/07/2009 02:50 PM -----

From: Jim Jones/DC/USEPA/US  
To: Edwards.Debbie@epamail.epa.gov, green.teresa@epa.gov  
Date: 07/07/2009 02:48 PM  
Subject: another items for Steve O

---

I think we'll want to add the Human Studies Settlement to our list of issues to brief Steve, It can be later on the list but I believe our current "deadline" is early August. Jim

Douglas  
Parsons/DC/USEPA/US  
09/04/2009 09:33 AM

To: Jordan.William  
cc  
bcc  
Subject: Fw: Human Studies Litigation

Let's talk about this possible outreach to EPW. Thanks, doug

----- Forwarded by Douglas Parsons/DC/USEPA/US on 09/04/2009 09:32 AM -----

From: David Piantanida/DC/USEPA/US  
To: Douglas Parsons/DC/USEPA/US@EPA  
Date: 09/04/2009 09:17 AM  
Subject: Re: Fw: Human Studies Litigation

---

OK - let's discuss when you have a minute.

David Piantanida, (202) 564-8318  
U.S. Environmental Protection Agency  
OCIR / Office of Congressional Affairs  
Piantanida.David@epa.gov

Douglas Parsons    I think folks would be glad to brief EP...    09/04/2009 09:15:02 AM

From: Douglas Parsons/DC/USEPA/US  
To: David Piantanida/DC/USEPA/US@EPA  
Date: 09/04/2009 09:15 AM  
Subject: Re: Fw: Human Studies Litigation

---

I think folks would be glad to brief EPW majority but would need to make sure OGC is ok. But I don't think we want to go up with ORD on this issue. I'll have to think about that some more.

doug

David Piantanida    Hey Doug, FYI - the OGC OPP attorn...    09/04/2009 08:51:26 AM

From: David Piantanida/DC/USEPA/US  
To: Douglas Parsons/DC/USEPA/US@EPA  
Date: 09/04/2009 08:51 AM  
Subject: Fw: Human Studies Litigation

---

Hey Doug,

FYI - the OGC OPP attorneys have been notified and I wanted to let you know that ORD is looking to get going with this initiative. I have notified the 3rd floor and will be giving EPW a heads-up.

David Piantanida, (202) 564-8318  
U.S. Environmental Protection Agency  
OCIR / Office of Congressional Affairs  
Piantanida.David@epa.gov

----- Forwarded by David Piantanida/DC/USEPA/US on 09/04/2009 08:45 AM -----

From: David Piantanida/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Cc: Byron Brown/DC/USEPA/US@EPA, Sven-Erik Kaiser/DC/USEPA/US@EPA  
Date: 09/03/2009 04:37 PM  
Subject: Re: Human Studies Litigation

---

Brenda and Keith,

I am the Congressional liaison for ORD and they are looking to get started with the "new and improved" version of the observational studies initiative. We have briefed EPW on this issue and ORD is poised to publish an RFA for children's exposure research. The other piece of this puzzle is the litigation/legal issue that I know you have been working on for years. Are you able to share where the litigation stands?

Thanks,

David Piantanida, (202) 564-8318  
U.S. Environmental Protection Agency  
OCIR / Office of Congressional Affairs  
Piantanida.David@epa.gov

Byron Brown	David, OGC's Pesticides and Toxic Su...	02/13/2009 12:32:43 PM
-------------	---	------------------------

From: Byron Brown/DC/USEPA/US  
To: David Piantanida/DC/USEPA/US@EPA  
Cc: Brenda Mallory/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 02/13/2009 12:32 PM  
Subject: Human Studies Litigation

---

David, OGC's Pesticides and Toxic Substances Law Office handles this issue. I've copied Brenda Mallory, who heads the law office, and Keith Matthews, who has worked on the litigation. They should be able to help assist you with preparing for the Congressional briefing.

**Douglas**  
**Parsons/DC/USEPA/US**  
06/01/2010 03:50 PM

To "Robert Perlis", "William Jordan"  
cc  
bcc  
Subject HS litigation

Hey bill or Bob---When will the human studies litigation be filed w the court? Thanks, doug

Jay  
Ellenberger/DC/USEPA/US  
02/18/2010 01:30 PM

To William Jordan  
cc  
bcc  
Subject Re: cab to the hill

Ok, good luck to you too

Jay

Jay Ellenberger, Deputy Director  
Field and External Affairs Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
703/305-7099  
Visit <http://www.epa.gov/pesticides>

William Jordan Thanks. I can't go; I need to attend a m... 02/18/2010 01:02:13 PM

From: William Jordan/DC/USEPA/US  
To: Jay Ellenberger/DC/USEPA/US@EPA  
Date: 02/18/2010 01:02 PM  
Subject: Re: cab to the hill

Thanks. I can't go; I need to attend a meeting with Mr. Sussman on Human Studies litigation.

Good luck,

**Bill**

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

Jay Ellenberger cathryn, rick k. and i are meeting at 2 d... 02/18/2010 12:51:50 PM

From: Jay Ellenberger/DC/USEPA/US  
To: William Jordan/DC/USEPA/US@EPA  
Date: 02/18/2010 12:51 PM  
Subject: cab to the hill

cathryn, rick k. and i are meeting at 2 down in the lobby. will you join us?

Jay

Jay Ellenberger, Deputy Director  
Field and External Affairs Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
703/305-7099  
Visit <http://www.epa.gov/pesticides>



**Jennifer Wills/DC/USEPA/US**

10/13/2009 11:19 AM

To Brenda Mallory

cc

bcc

Subject Accepted: OPPT Interest in Human Studies Settlement

Jim Jones/DC/USEPA/US

04/10/2009 10:15 AM

To Angela Huskey

cc Brenda Mallory, Byron Brown, John Carley, Jonathan Fleuchaus, Keith Matthews, Kelly Sherman, Philip Ross, William Jordan

bcc

Subject Re: Motion for stay in human studies case

thanks; when do you expect we'd hear from the court? Jim

Angela Huskey

[The motion for stay in NRDC v. EPA is...](#)

04/10/2009 09:27:33 AM

From: Angela Huskey/DC/USEPA/US  
To: Jim Jones/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA, John Carley/DC/USEPA/US@EPA, Kelly Sherman/DC/USEPA/US@EPA, Byron Brown/DC/USEPA/US@EPA  
Cc: Keith Matthews/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA  
Date: 04/10/2009 09:27 AM  
Subject: Motion for stay in human studies case

---

The motion for stay in [NRDC v. EPA](#) is being filed in the Second Circuit today.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

**Jim Jones/DC/USEPA/US**

10/12/2010 05:01 PM

To Joyce Crowley

cc Steven Bradbury, Leslye Fraser, Brenda Mallory, Jonathan  
Fleuchaus, Steve Owens

bcc

Subject Human Studies Rule

Joyce, could you please schedule a meeting with Steve Owens, Steve Bradbury and OGC tomorrow (wed) after 1pm EDT? I will not be able to join but that is ok. The topic is the Court decision on Human Studies litigation. Thanks. Jim

**John Carley/DC/USEPA/US**

10/15/2009 08:21 AM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

**John Carley/DC/USEPA/US**  
01/04/2010 09:48 AM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**John Carley/DC/USEPA/US**

10/17/2006 12:16 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss response for Human Studies litigation

**Jonathan  
Fleuchaus/DC/USEPA/US**  
10/15/2009 07:58 AM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

**Jonathan  
Fleuchaus/DC/USEPA/US**  
11/10/2009 02:42 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss human studies settlement

**Jonathan  
Fleuchaus/DC/USEPA/US**  
12/29/2009 03:23 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**Jonathan  
Fleuchaus/DC/USEPA/US**  
10/12/2010 05:05 PM

To: Angela Huskey  
cc  
bcc  
Subject: Fw: Human Studies Rule

----- Forwarded by Jonathan Fleuchaus/DC/USEPA/US on 10/12/2010 05:01 PM -----

From: Jim Jones/DC/USEPA/US  
To: Joyce Crowley/DC/USEPA/US@EPA  
Cc: Steven Bradbury/DC/USEPA/US@EPA, Leslye Fraser/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, Steve Owens/DC/USEPA/US@EPA  
Date: 10/12/2010 05:01 PM  
Subject: Human Studies Rule

---

Joyce, could you please schedule a meeting with Steve Owens, Steve Bradbury and OGC tomorrow (wed) after 1pm EDT? I will not be able to join but that is ok. The topic is the Court decision on Human Studies litigation. Thanks. Jim

Jonathan  
Fleuchaus/DC/USEPA/US  
11/17/2009 11:39 AM

To Angela Huskey  
cc Brenda Mallory, Keith Matthews, Robin Spriggs  
bcc  
Subject Re: HEADS UP - Human Studies Litigation Mtg.

that time is fine with me

Angela Huskey I can be available at that time. \*\*\*\*\* ... 11/17/2009 11:32:30 AM

From: Angela Huskey/DC/USEPA/US  
To: Robin Spriggs/DC/USEPA/US@EPA  
Cc: Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 11/17/2009 11:32 AM  
Subject: Re: HEADS UP - Human Studies Litigation Mtg.

I can be available at that time.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

Robin Spriggs Avi has another meeting at OMB and w... 11/17/2009 10:50:20 AM

From: Robin Spriggs/DC/USEPA/US  
To: Angela Huskey/DC/USEPA/US@EPA, Brenda Mallory/DC/USEPA/US@EPA, Jonathan Fleuchaus/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA  
Date: 11/17/2009 10:50 AM  
Subject: HEADS UP - Human Studies Litigation Mtg.

Avi has another meeting at OMB and would like to start the Human Studies meeting a little later would 4:30 today work for you guys?

**Jonathan  
Fleuchaus/DC/USEPA/US**  
03/31/2010 12:13 PM

To Brenda Mallory  
cc  
bcc  
Subject OMB --- did response on Human studies settlement go over?

**Jonathan**  
**Fleuchaus/DC/USEPA/US**  
01/19/2010 10:24 AM

To Scott Fulton  
cc  
bcc  
Subject Accepted: Discussion on Human Studies Settlement

**Jonathan**  
**Fleuchaus/DC/USEPA/US**  
01/19/2010 11:58 AM

To Scott Fulton  
cc  
bcc  
Subject Accepted: Discussion on Human Studies Settlement

**Jonathan**  
**Fleuchaus/DC/USEPA/US**  
01/22/2010 08:01 AM

To Scott Fulton  
cc  
bcc  
Subject Accepted: Discussion on Human Studies Settlement

Joy  
Schnackenberg/DC/USEPA/U  
S

10/14/2009 04:31 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

Joy  
Schnackenberg/DC/USEPA/US

08/10/2009 02:21 PM

To Laura Parsons

cc James Parker, Angela Huskey

bcc

Subject Re: James Parker and I have amitraz.  
amitraz?

Re: who has

Hey guys:

Do you want to give Angela Huskey from OGC a call. She's the OGC lead for settlement negotiations with NRDC regarding the human studies rule. These negotiations may directly affect amitraz, so it would be great for you guys to tell her the status of the chemical.

Thanks!

-----  
Joy Schnackenberg  
Chemical Review Manager  
Office of Pesticide Programs  
Special Review and Reregistration Branch  
USEPA 7508P  
Ariel Rios Building  
1200 Pennsylvania Avenue N.W.  
Washington D.C. 20460  
Voice: 703-308-8072 Fax: 703-308-8005

Laura Parsons

08/10/2009 01:52:39 PM

From: Laura Parsons/DC/USEPA/US  
To: Joy Schnackenberg/DC/USEPA/US@EPA  
Cc: James Parker/DC/USEPA/US@EPA  
Date: 08/10/2009 01:52 PM  
Subject: James Parker and I have amitraz. Re: who has amitraz?

Joy Schnackenberg

08/10/2009 01:50:56 PM

From: Joy Schnackenberg/DC/USEPA/US  
To: OPP SRRD  
Date: 08/10/2009 01:50 PM  
Subject: who has amitraz?

-----  
Joy Schnackenberg  
Chemical Review Manager  
Office of Pesticide Programs  
Special Review and Reregistration Branch  
USEPA 7508P  
Ariel Rios Building  
1200 Pennsylvania Avenue N.W.  
Washington D.C. 20460  
Voice: 703-308-8072 Fax: 703-308-8005



**Steve Owens/DC/USEPA/US**  
Sent by: Joyce Crowley

10/13/2010 11:41 AM

To Brenda Mallory, Jonathan Fleuchaus, Leslye Fraser, Steven  
Bradbury  
cc Jim Jones  
bcc

Subject Information Update - Location has changed: Court Decision  
on Human Studies Litigation / Phone Call

please schedule a meeting with Steve Owens, Steve Bradbury and OGC tomorrow (wed) after 1pm EDT?  
I will not be able to join but that is ok. The topic is the Court decision on Human Studies litigation. Thanks.  
Jim

**Steve Owens/DC/USEPA/US**  
Sent by: Joyce Crowley

10/13/2010 07:16 AM

To Brenda Mallory, Jonathan Fleuchaus, Leslye Fraser, Steven  
Bradbury  
cc Jim Jones  
bcc

Subject Invitation: Court Decision on Human Studies Litigation /  
Phone Call (Oct 13 02:00 PM EDT in Phone call)

please schedule a meeting with Steve Owens, Steve Bradbury and OGC tomorrow (wed) after 1pm EDT?  
I will not be able to join but that is ok. The topic is the Court decision on Human Studies litigation. Thanks.  
Jim

Joyce Crowley/DC/USEPA/US

02/24/2010 01:13 PM

To William Jordan

cc

bcc

Subject Fw: Forwarded meeting Notice from Avi Garbow:  
Rescheduled: Human Studies Settlement - OMB Interface  
(Feb 25 04:30 PM EST in Room 4045/DC-Ariel  
Rios-OGC@EPA)

Bill--

Jim has a hearing prep meeting scheduled from 3:00 - 4:00 on Thursday, Feb 25 and he would like for you to attend this meeting for him until he arrives. Call or email me if you can't make it.

Joyce

----- Forwarded by Joyce Crowley/DC/USEPA/US on 02/24/2010 12:57 PM -----

From: Jim Jones/DC/USEPA/US  
To: Joyce Crowley/DC/USEPA/US, Harriett Haymon/DC/USEPA/US, Denise Adams/DC/USEPA/US,  
Lynda Garland/DC/USEPA/US  
Date: 02/24/2010 11:05 AM  
Subject: Forwarded meeting Notice from Avi Garbow: Rescheduled: Human Studies Settlement - OMB  
Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)


---

A Meeting Request for Jim Jones requires your attention.

The subject of the notice is

Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room  
4045/DC-Ariel Rios-OGC@EPA)

The meeting is chaired by Avi Garbow

Please process this request -> 

Joyce Crowley/DC/USEPA/US

02/24/2010 02:00 PM

To William Jordan

cc

bcc

Subject Re: Fw: Forwarded meeting Notice from Avi Garbow:  
Rescheduled: Human Studies Settlement - OMB Interface  
(Feb 25 04:30 PM EST in Room 4045/DC-Ariel  
Rios-OGC@EPA)

My mistake -- Jim's meeting is from 4:00 - 5:00.

William Jordan

[I have added this to my calendar and w...](#)

02/24/2010 01:53:26 PM

From: William Jordan/DC/USEPA/US  
To: Joyce Crowley/DC/USEPA/US@EPA  
Date: 02/24/2010 01:53 PM  
Subject: Re: Fw: Forwarded meeting Notice from Avi Garbow: Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)

---

I have added this to my calendar and will attend.

I note that the meeting starts at 4:30 and your message indicates Jim's prep session ends at 4:00 PM. That does not seem like a conflict to me, unless the prep session runs significantly longer than it is scheduled to last.

Thanks,

Bill

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

Joyce Crowley

[Bill-- Jim has a hearing prep meeting sc...](#)

02/24/2010 01:13:39 PM

From: Joyce Crowley/DC/USEPA/US  
To: William Jordan/DC/USEPA/US@EPA  
Date: 02/24/2010 01:13 PM  
Subject: Fw: Forwarded meeting Notice from Avi Garbow: Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)

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----- Forwarded by Joyce Crowley/DC/USEPA/US on 02/24/2010 12:57 PM -----

From: Jim Jones/DC/USEPA/US  
To: Joyce Crowley/DC/USEPA/US, Harriett Haymon/DC/USEPA/US, Denise Adams/DC/USEPA/US, Lynda Garland/DC/USEPA/US


Date: 02/24/2010 11:05 AM  
Subject: Forwarded meeting Notice from Avi Garbow: Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)

---

A Meeting Request for Jim Jones requires your attention.

The subject of the notice is  
Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room  
4045/DC-Ariel Rios-OGC@EPA)

The meeting is chaired by Avi Garbow

Please process this request -> 

Keith Matthews/DC/USEPA/US

To angela huskey, ross.philip

cc

05/27/2009 01:57 PM

bcc

Subject Fw: Human Studies Settlement - Conference Call

Can we get together at 3:30 to confer on today's call? It looks like 7500 is available.

----- Forwarded by Keith Matthews/DC/USEPA/US on 05/27/2009 01:54 PM -----

## Human Studies Settlement - Conference Call

Wed 05/27/2009 4:00 PM - 5:00 PM

Attendance is for Keith Matthews

Chair: Brenda Mallory/DC/USEPA/US

Sent By: Khisa Lee/DC/USEPA/US

Rooms: Conf Rm 7500/DC-Ariel Rios-OGC@EPA

This entry has an alarm. The alarm will go off before the entry starts.

Required:

Angela Huskey/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA

Description

Personal Notes



**Keith Matthews/DC/USEPA/US**

To Angela Huskey

cc

10/15/2009 08:49 AM

bcc

Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

**Keith Matthews/DC/USEPA/US**

To Angela Huskey

cc

11/09/2009 04:32 PM

bcc

Subject Accepted: Discuss human studies settlement

**Keith Matthews/DC/USEPA/US**

To Angela Huskey

cc

12/22/2009 04:00 PM

bcc

Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**Keith Matthews/DC/USEPA/US**

To Angela Huskey

cc

10/17/2006 12:01 PM

bcc

Subject Accepted: Discuss response for Human Studies litigation

**Keith Matthews/DC/USEPA/US**

To Angela Huskey

cc

08/09/2006 02:28 PM

bcc

Subject Accepted: Human Studies Litigation

**Keith Matthews/DC/USEPA/US**

To Brenda Mallory

cc

05/27/2009 11:14 AM

bcc

Subject Accepted: Human Studies Settlement - Conference Call

**Keith Matthews/DC/USEPA/US**

To Brenda Mallory

cc

06/02/2009 10:50 AM

bcc

Subject Accepted: Human Studies Settlement Conference Call

**Keith Matthews/DC/USEPA/US**

To Brenda Mallory

cc

05/22/2007 11:32 AM

bcc

Subject Accepted: Motion to Join EPA in Human Studies Case

**Keith Matthews/DC/USEPA/US**

To Brenda Mallory

cc

10/18/2009 01:25 PM

bcc

Subject Accepted: OPPT Interest in Human Studies Settlement

**Keith Matthews/DC/USEPA/US**

To Brenda Mallory

05/02/2006 10:14 AM

cc

bcc

Subject Re: Anything for OGC Senior Staff?

That's right. I tend to think of big-ticket items like briefs and decisions, but this is a significant step in the litigation.


Brenda Mallory/DC/USEPA/US

**Brenda  
Mallory/DC/USEPA/US**

To Keith Matthews/DC/USEPA/US@EPA

05/02/2006 09:45 AM

cc

Subject Re: Anything for OGC Senior Staff? 

I should probably mention the Motion to Dismiss in the Human Studies case.


Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov  
Keith Matthews/DC/USEPA/US

**Keith  
Matthews/DC/USEPA/US**

To Brenda Mallory/DC/USEPA/US@EPA

05/02/2006 09:32 AM

cc

Subject Re: Anything for OGC Senior Staff? 

Nothing here.

Brenda Mallory/DC/USEPA/US

**Brenda  
Mallory/DC/USEPA/US**

To Brian Grant/DC/USEPA/US@EPA, Robert  
Perlis/DC/USEPA/US@EPA, Keith  
Matthews/DC/USEPA/US@EPA

05/02/2006 08:24 AM

cc

Subject Anything for OGC Senior Staff?

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
[mallory.brenda@epa.gov](mailto:mallory.brenda@epa.gov)

**Keith Matthews/DC/USEPA/US**

To Brenda Mallory

03/28/2006 10:41 AM

cc

bcc

Subject Re: Topics for OPPTS and OGC Senior Staff

You might mention that the answer is due in 60 days on the Human Studies litigation in the N.D. of Ca., but that we expect to get that case stayed or dismissed w/o p. Also, do we know how aware Susie is of the back and forth with amvac on ddvp and the HSRB? She may appreciate a head's up.  
Brenda Mallory/DC/USEPA/US

**Brenda**

**Mallory/DC/USEPA/US**

03/27/2006 06:37 PM

"Brian Grant" <grant.brian@epa.gov>, "Keith Matthews"

To <matthews.keith@epa.gov>, "Robert Perlis"

<perlis.robert@epa.gov>

cc

Subject Topics for OPPTS and OGC Senior Staff

OPPTS - Wabash decision, selection of Second Circuit for Human Studies case, Status of Lead docket issue

OGC - the first two above - use to remind Ann that we need feedback on Wabash

Other??

**Keith Matthews/DC/USEPA/US**

To mallory.brenda, Robert Perlis

cc

03/01/2006 02:57 PM

bcc

Subject Human Studies Litigation

By the way, Bill heard this morning at a public meeting that the litigation in the 9th Circuit was defensively filed in U.S. District Court, so that plaintiffs have all bases covered.

**Keith Matthews/DC/USEPA/US**

11/17/2009 10:52 AM

To Robin Spriggs, Angela Huskey, Brenda Mallory, Jonathan Fleuchaus

cc

bcc

Subject Re: HEADS UP - Human Studies Litigation Mtg.

This is actually better for me.  
Robin Spriggs

----- Original Message -----

**From:** Robin Spriggs

**Sent:** 11/17/2009 10:50 AM EST

**To:** Angela Huskey; Brenda Mallory; Jonathan Fleuchaus; Keith Matthews

**Subject:** HEADS UP - Human Studies Litigation Mtg.

Avi has another meeting at OMB and would like to start the Human Studies meeting a little later would 4:30 today work for you guys?

**Keith Matthews/DC/USEPA/US**

To Scott Fulton

cc

01/28/2010 12:06 PM

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Kelly Sherman/DC/USEPA/US**

10/14/2009 04:18 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

**Kelly Sherman/DC/USEPA/US**  
12/22/2009 04:00 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

Kelly Sherman/DC/USEPA/US  
12/22/2009 04:03 PM

To Angela Huskey, John Carley, Keith Matthews, Philip Ross,  
William Jordan  
cc  
bcc  
Subject Re: Discuss options for aldicarb and amitraz in human  
studies settlement

I've reserved 12621 for the meeting. See you then. Happy Holidays.

----- Forwarded by Kelly Sherman/DC/USEPA/US on 12/22/2009 04:02 PM -----

## Discuss options for aldicarb and amitraz in human studies settlement

Mon 01/04/2010 2:00 PM - 3:00 PM

Attendance is for Kelly Sherman

Chair: Angela Huskey/DC/USEPA/US

No Location Information

Required:

John Carley/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Kelly Sherman/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA

### Description

If someone can find a room at PY, I can come over for the meeting. Otherwise, we can do a conference call.

### Personal Notes



**Kevin Minoli/DC/USEPA/US**  
07/20/2006 12:22 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Human Studies Litigation

**Brenda Mallory/DC/USEPA/US**

To

Sent by: Khisa Lee

cc

bcc

08/17/2009 03:47 PM

Subject Human Studies Settlement

**Meeting**

Date 08/18/2009

Time 12:00:00 PM to 01:00:00 PM

Chair Brenda Mallory

Invitees

Required Angela Huskey; Philip Ross

Optional Keith Matthews

FYI

Location

**Brenda Mallory/DC/USEPA/US**

To

Sent by: Khisa Lee

cc

bcc

05/27/2009 09:25 AM

Subject Human Studies Settlement - Conference Call

**Meeting**

Date 05/27/2009

Time 04:00:00 PM to 05:00:00 PM

Chair Brenda Mallory

Invitees

Required Angela Huskey; Keith Matthews; Philip Ross

Optional

FYI

Location

**Brenda Mallory/DC/USEPA/US**

To

Sent by: Khisa Lee

cc

bcc

06/02/2009 10:02 AM

Subject Human Studies Settlement Conference Call

**Meeting**

Date 06/04/2009

Time 02:00:00 PM to 03:00:00 PM

Chair Brenda Mallory

Invitees

Required Angela Huskey; Keith Matthews; Philip Ross

Optional

FYI

(b) (6)



**Brenda Mallory/DC/USEPA/US**

To

Sent by: Khisa Lee

cc

bcc

05/22/2007 11:25 AM

Subject Motion to Join EPA in Human Studies Case

**Meeting**

Date 05/22/2007

Time 04:30:00 PM to 05:00:00 PM

Chair Brenda Mallory

Invitees

Required Andrew Simons; Brian Grant; Keith Matthews

Optional

FYI

Location Brenda's Office

**Brenda Mallory/DC/USEPA/US**

To

Sent by: Khisa Lee

cc

bcc

10/13/2009 10:44 AM

Subject OPPT Interest in Human Studies Settlement

**Meeting**

Date 10/15/2009

Time 11:00:00 AM to 12:00:00 PM

Chair Brenda Mallory

Invitees

Required Angela Huskey; Jennifer Wills

Optional Keith Matthews; Philip Ross

FYI

Location

**Laura Parsons/DC/USEPA/US**  
10/14/2009 04:47 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

**Laura Parsons/DC/USEPA/US**  
12/29/2009 03:17 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**Lee Tyner/DC/USEPA/US**

10/17/2006 01:49 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss response for Human Studies litigation

Lee Tyner/DC/USEPA/US  
10/23/2006 10:15 AM

To Angela Huskey  
cc  
bcc  
Subject Fw: Discuss response for Human Studies litigation

Would it be ok to invite Roger Cortesi of ORD to this?

----- Forwarded by Lee Tyner/DC/USEPA/US on 10/23/2006 10:15 AM -----

Calendar Entry

## Meeting

☐ Notify me  
☐ Mark Private ☐ Pencil In

Subject	Discuss response for Human Studies litigation							
When	<table><tr><td>Starts</td><td>Mon 10/23/2006</td><td>02:00 PM</td><td rowspan="2">1 hour</td></tr><tr><td>Ends</td><td>Mon 10/23/2006</td><td>03:00 PM</td></tr></table>	Starts	Mon 10/23/2006	02:00 PM	1 hour	Ends	Mon 10/23/2006	03:00 PM
Starts	Mon 10/23/2006	02:00 PM	1 hour					
Ends	Mon 10/23/2006	03:00 PM						
Invitees	<table><tr><td>Required (to)</td><td>John Carley/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA</td></tr><tr><td>Optional (cc)</td><td>Lee Tyner/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA</td></tr></table>	Required (to)	John Carley/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA	Optional (cc)	Lee Tyner/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA			
Required (to)	John Carley/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA							
Optional (cc)	Lee Tyner/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA							

Chair	Angela Huskey/DC/USEPA/US				
Where	<table><tr><td>Location</td><td></td></tr><tr><td>Rooms</td><td>Conf Rm 7346/DC-Ariel Rios-OGC@EPA</td></tr></table>	Location		Rooms	Conf Rm 7346/DC-Ariel Rios-OGC@EPA
Location					
Rooms	Conf Rm 7346/DC-Ariel Rios-OGC@EPA				
Categorize					

Description	
-------------	--

Since we're likely to have more people attending from OGC now, I've gone ahead and set up a conference room over here.

Your Notes	
------------	--

**Lesley Schaaff/DC/USEPA/US**

02/16/2010 02:14 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies settlement

**Lesley Schaaff/DC/USEPA/US**  
02/17/2010 04:40 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss human studies settlement

**Lesley Schaaff/DC/USEPA/US**

11/10/2009 10:44 AM

To Brenda Mallory, Charlotte Bertrand

cc

bcc

Subject any news on human subjects settlement? thanks.

Lesley Schaaff  
Director, Policy & Regulatory Analysis Division  
Office of Policy, Economics & Innovation  
Office of the Administrator  
U.S. Environmental Protection Agency  
Phone: 202-564-6567  
Fax: 202-564-7303  
[schaaff.lesley@epa.gov](mailto:schaaff.lesley@epa.gov)

Leslye Fraser/DC/USEPA/US

05/18/2011 06:03 PM

To Chris Kaczmarek

cc Angela Huskey, Jonathan Fleuchaus

bcc

Subject Re: Fw: Broadcast: Human Studies (May 24 02:00 PM EDT in 3309 ARN)

yes; thanks - and I will need a pre-brief; thanks

Leslye M. Fraser  
Associate General Counsel  
Pesticides and Toxic Substances Law Office  
EPA Office of General Counsel  
(202) 564-5375 phone  
(202) 564-5644 fax  
Fraser.Leslye@epa.gov

Chris Kaczmarek

Leslye, although it is not crystal clear...

05/18/2011 05:53:44 PM

From: Chris Kaczmarek/DC/USEPA/US  
To: Leslye Fraser/DC/USEPA/US@EPA  
Cc: Jonathan Fleuchaus/DC/USEPA/US@EPA, Angela Huskey/DC/USEPA/US@EPA  
Date: 05/18/2011 05:53 PM  
Subject: Fw: Broadcast: Human Studies (May 24 02:00 PM EDT in 3309 ARN)

Leslye, although it is not crystal clear to me what exactly this is about, I am assuming that you should be added to this invite as well. If that is the case, I will contact Sussman's secretary.

Jon and Angela, we will need you to bring us up to speed as to exactly what is going on with this. I recall seeing an earlier email that something was up involving human studies, but that email did not provide much in the way of details. Perhaps we should schedule a meeting amongst the 4 of us for Monday, May 23rd?

----- Forwarded by Chris Kaczmarek/DC/USEPA/US on 05/18/2011 05:50 PM -----

**Broadcast: Human Studies**

**Tue 05/24/2011 2:00 PM - 3:00 PM**

Attendance is **required** for Chris Kaczmarek

Chair: **Bob Sussman/DC/USEPA/US**

Sent By: **Georgia Bednar/DC/USEPA/US**

Location: 3309 ARN

**Bob Sussman** has invited you to a meeting. You have not added this entry to your calendar.

Bill Diamond/DC/USEPA/US@EPA, Chris Kaczmarek/DC/USEPA/US@EPA, Kelly

Required:	Sherman/DC/USEPA/US@EPA, Steve Owens/DC/USEPA/US@EPA, Steven Bradbury/DC/USEPA/US@EPA, William Jordan/DC/USEPA/US@EPA
Optional:	Ann Campbell/DC/USEPA/US@EPA, Georgia Bednar/DC/USEPA/US@EPA, KarenL Martin/DC/USEPA/US@EPA, Mary Hanley/DC/USEPA/US@EPA, Nena Shaw/DC/USEPA/US@EPA, Venu Ghanta/DC/USEPA/US@EPA

## Description

Subject: To discuss the **Human Studies**

Time: 30 Minute Meeting

Let me know when you get a chance. Thanks

### **Recommended Invitee List** (Possibly a few more names to follow)

From:  
Bob Sussman/DC/USEPA/US,

To:  
Steve Owens/DC/USEPA/US, Bill Diamond/DC/USEPA/US, Steven Bradbury/DC/USEPA/US, William Jordan/DC/USEPA/US, Chris Kaczmarek/DC/USEPA/US, Kelly Sherman/DC/USEPA/US,

Cc:  
Mary Hanley/DC/USEPA/US, Margie Fehrenbach/DC/USEPA/US, Karen Angulo/DC/USEPA/US, Debby Sisco/DC/USEPA/US, Teresa Green/DC/USEPA/US, Douglas Parsons/DC/USEPA/US,

**Lisa**  
**Heinzerling/DC/USEPA/US**  
04/09/2010 02:05 PM

To Bob Sussman, Brenda Mallory, Scott Fulton  
cc Bob Perciasepe  
bcc  
Subject Human subjects settlement

**Meeting**

Date 04/12/2010  
Time 09:15:00 AM to 09:30:00 AM  
Chair Lisa Heinzerling  
Invitees  
Required Bob Sussman; Brenda Mallory; Scott Fulton  
Optional Bob Perciasepe  
FYI  
Location ARN 3513

**Lisa**  
**Heinzerling/DC/USEPA/US**

03/11/2010 07:04 PM

To "Avi Garbow", "Brenda Mallory"

cc "Nicole Owens"

bcc

Subject Human subjects settlement

OIRA says we may not transmit this through ROCIS under EO, must transmit through OMB OGC. They say two weeks or less.

Let us know if you need anything. I take it you'll transmit to OMB OGC?

Thanks.

**Michael**  
**Metzger/DC/USEPA/US**  
10/14/2009 04:18 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

Michele Knorr/DC/USEPA/US  
06/28/2010 01:57 PM

To OGC PTSLO  
cc  
bcc  
Subject Fw: EPA Pesticide Program Update 06/18/2010-1) EPA Settles Lawsuit over Its 2006 Human Subjects Protections Rule;2) NPDES Webcast Rescheduled for June 24;3) Pesticide Fed. Reg. Items for the Wk of June14-18;4) Registration Decisions Opened for Public Comment for the Week of June 14, 2010

Michele Knorr  
U.S. EPA  
Office of General Counsel  
Pesticides and Toxic Substances Law Office  
202-564-5631

----- Forwarded by Michele Knorr/DC/USEPA/US on 06/28/2010 01:57 PM -----

From: Mary-Jean Lormand/DC/USEPA/US  
To: lormand.mary-jean@epa.gov  
Date: 06/18/2010 04:16 PM  
Subject: EPA Pesticide Program Update 06/18/2010-1) EPA Settles Lawsuit over Its 2006 Human Subjects Protections Rule;2) NPDES Webcast Rescheduled for June 24;3) Pesticide Fed. Reg. Items for the Wk of June14-18;4) Registration Decisions Opened for Public Comment for the Week of June 14, 2010

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**EPA Pesticide Program Updates  
from EPA's Office of Pesticide Programs 06/18/2010**  
<http://www.epa.gov/pesticides>

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**IN THIS UPDATE:**

- 1) EPA Settles Lawsuit over Its 2006 Human Subjects Protections Rule**
- 2) NPDES Webcast Rescheduled for June 24**
- 3) Pesticide *Federal Register* Items for the Week of June14-18, 2010**
- 4) Registration Decisions Opened for Public Comment for the Week of June 14, 2010:**  
[\*\*Aminocyclopyrachlor\*\*](#)

\*\*\*\*\*

**1) EPA Settles Lawsuit over Its 2006 Human Subjects Protections Rule**

EPA has settled a lawsuit over its 2006 regulation that established protections for subjects of human research. Under the settlement, EPA agrees to propose amendments to the rule to formalize many current procedures that EPA has been following as it implemented the 2006 rule. The proposal would also address the three principal areas identified by the petitioners: the scope of the rule, its consistency with the 2004 National Academy of Science recommendations, and its consistency with the Nuremberg Code.

As required by [the Human Subjects Protections Rule settlement](#), EPA will publish the proposed amendments in a *Federal Register* notice before January 16, 2011, and open

a public comment period at the same time. The amendments will be finalized by December 16, 2011.

\*\*\*\*\*

## **2) NPDES Webcast Rescheduled for June 24**

On Thursday, June 24, 2010, from 1:00 pm - 3:00 pm, ET, the Office of Water of the U.S. Environmental Protection Agency will hold a Webinar on the National Pollutant Discharge Elimination System (NPDES) draft Pesticides General Permit (PGP) currently out for public comment. This Webinar is intended to provide an overview of the Agency's draft permit and to answer questions related to it to help stakeholders better formulate comments on the permit. Interested parties are invited to listen and watch the broadcast. To view the Webinar, please register at the following Web site:

[http://cfpub.epa.gov/npdes/courseinfo.cfm?program\\_id=0&outreach\\_id=506&schedule\\_id=1089](http://cfpub.epa.gov/npdes/courseinfo.cfm?program_id=0&outreach_id=506&schedule_id=1089)

. If you registered previously for this broadcast, you do not need to do so again but can proceed directly to the Web site anytime after 12:50 pm.

\*\*\*\*\*

## **3) Pesticide *Federal Register* Items for the Week of June 14-18, 2010**

The following 11 items related to pesticides were published in the *Federal Register* during the past week:

- 1) Pesticide Management and Disposal; Standards for Pesticide Containers and Containment; Change to Labeling Compliance Date
- 2) Pesticide Management and Disposal; Standards for Pesticide Containers and Containment; Change to Labeling Compliance Date
- 3) Sodium 1, 4-Dialkyl Sulfosuccinates; Exemption from the Requirement of a Tolerance
- 4) *Bacillus thuringiensis* eCry3.1Ab Protein in Corn; Temporary Exemption from the Requirement of a Tolerance
- 5) Notice of Intent to Suspend Certain Pesticide Registrations
- 6) Pesticide Products; Registration Applications
- 7) Pesticides; Availability of Updated Schedule for Registration Review
- 8) Product Cancellation Order for Certain Pesticide Registrations; Correction
- 9) Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations
- 10) Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations
- 11) Pesticides; Draft Guidance for Pesticide Registrants on False or Misleading Pesticide Product Brand Names; Extension of Comment Period

### **1) Pesticide Management and Disposal; Standards for Pesticide Containers and Containment; Change to Labeling Compliance Date**

**Date of publication:** June 15, 2010

**Citation:** Volume 75, Number 114; Page 33705-33708

<http://edocket.access.gpo.gov/2010/2010-14403.htm>

**Purpose:** EPA is amending the pesticide container and containment regulations to provide a 4-month extension of the 40 CFR 156.159 labeling compliance date from August 16, 2010 to December 16, 2010. This change is being made because there is insufficient time for pesticide registrants, EPA and states to complete the label amendments. This change will avoid the temporary removal of a significant number of pesticides from the market while a 1-year extension proposed elsewhere in today's Federal Register proceeds through the rulemaking

process, and while pesticide registrants, EPA and states work to update the pesticide labels to comply with the label requirements in the container and containment regulations.

**Chemical(s):** N/A

**Comments:** EPA has established a docket for this action under docket identification number EPA-HQ-OPP-2005-0327. This final rule is effective August 16, 2010.

**Contact:** Nancy Fitz, Field and External Affairs Division (FEAD) (7506P), Office of Pesticide Programs, telephone number: (703) 305-7385; fax number: (703) 308-2962; e-mail address: fitz.nancy@epa.gov.

## **2) Pesticide Management and Disposal; Standards for Pesticide Containers and Containment; Proposed Change to Labeling Compliance Date**

**Date of publication:** June 15, 2010

**Citation:** Volume 75, Number 114; Page 33744-33747  
<http://edocket.access.gpo.gov/2010/2010-14401.htm>

**Purpose:** EPA is proposing to amend the pesticide container and containment regulations to provide a 1-year extension of the 40 CFR 156.159 labeling compliance date from August 16, 2010 to August 16, 2011. This change is being proposed to address concerns raised by stakeholders and as a result of further Agency consideration.

**Chemical(s):** N/A

**Comments:** Submit your comments, identified by docket identification number EPA-HQ-OPP-2005-0327, by one of the methods listed in the Federal Register Notice. Comments must be received on or before July 15, 2010.

**Contact:** Nancy Fitz, Field and External Affairs Division (FEAD) (7506P), Office of Pesticide Programs, telephone number: (703) 305-7385; fax number: (703) 308-2962; e-mail address: fitz.nancy@epa.gov.

## **3) Sodium 1, 4-Dialkyl Sulfosuccinates; Exemption from the Requirement of a Tolerance**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34045-34049  
<http://edocket.access.gpo.gov/2010/2010-14093.htm>

**Purpose:** This regulation establishes an exemption from the requirement of a tolerance for residues of sodium 1, 4-dialkyl sulfosuccinates including sodium 1, 4-diethyl sulfosuccinate (CAS Reg. No. 3006153); sodium 1, 4-diisobutyl sulfosuccinate (CAS Reg. No. 127399); and sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922805) when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals under 40 CFR 180.910 and 40 CFR 180.930, respectively. The Joint Inerts Task Force, Cluster Support Team 13 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of the sodium 1, 4-dialkyl sulfosuccinates.

**Chemical(s):** Sodium 1, 4-Dialkyl Sulfosuccinates

**Comments:** EPA has established a docket for this action under docket identification number EPA-HQ-OPP-2008-0739. This regulation is effective June 16, 2010. Objections and requests for hearings must be received on or before August 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178.

**Contact:** Karen Samek, Registration Division (7505P), Office of Pesticide Programs, telephone number: (703) 3478825; e-mail address: samek.karen@epa.gov.

## **4) Bacillus thuringiensis eCry3.1Ab Protein in Corn; Temporary Exemption from the Requirement of a Tolerance**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34040-34045

<http://edocket.access.gpo.gov/2010/2010-14330.htm>

**Purpose:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop, when used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit 67979-EUP-8. Syngenta Seeds, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting a temporary exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn under the FFDCA. The temporary tolerance exemption expires on June 1, 2012.

**Chemical(s):** *Bacillus thuringiensis* eCry3.1Ab Protein

**Comments:** EPA has established a docket for this action under docket identification number EPA-HQ-OPP-2009-0609. This regulation is effective June 16, 2010. Objections and requests for hearings must be received on or before August 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178.

**Contact:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), telephone number: (703) 3088715; e-mail address: [mendelsohn.mike@epa.gov](mailto:mendelsohn.mike@epa.gov).

## **5) Notice of Intent to Suspend Certain Pesticide Registrations**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34111-34114

<http://edocket.access.gpo.gov/2010/2010-14331.htm>

**Purpose:** This notice, pursuant to section 6(f)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, publishes a Notice of Intent to Suspend issued by EPA pursuant to section 3(c)(2)(B) of FIFRA. The Notice of Intent to Suspend was issued following the Agency's issuance of a Data Call-In notice (DCI), which required the registrant of the affected pesticide product containing a certain pesticide active ingredient to take appropriate steps to secure certain data, and following the registrant failure to submit these data or to take other appropriate steps to secure the required data. The subject data were determined to be required to maintain in effect the existing registration of the affected product. Failure to comply with the data requirements of a DCI is a basis for suspension of the affected registration under section 3(c)(2)(B) of FIFRA.

**Chemical(s):** Benzisothiazolin\*

**Comments:** EPA has established a docket for this action under docket identification number EPA-HQ-OPP-2010-0443. The Notice of Intent to Suspend included in this Federal Register notice will become a final and effective suspension order automatically by operation of law 30 days after the date of the registrant's receipt of the mailed Notice of Intent to Suspend or 30 days after the date of publication of this notice in the Federal Register. (if the mailed Notice of Intent to Suspend is returned to the Administrator as undeliverable, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery to the registrant after making reasonable efforts to do so), unless during that time a timely and adequate request for a hearing is made by a person adversely affected by the Notice of Intent to Suspend or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the Notice of Intent to Suspend. Unit IV. explains what must be done to avoid suspension under this notice (i.e., how to request a hearing or how to comply fully with the requirements that served as a basis for the Notice of Intent to Suspend).

**Contact:** Terria Northern, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, telephone number: (703) 3057093; e-mail address: [northern.terria@epa.gov](mailto:northern.terria@epa.gov).

## **6) Pesticide Products; Registration Applications**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34114-34115

<http://edocket.access.gpo.gov/2010/2010-14521.htm>

**Purpose:** EPA has received applications to register pesticide products containing active ingredients not included in any previously registered pesticide products. Pursuant to the provisions of section 3(c) (4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

**Chemical(s):** various

**Comments:** Submit your comments, identified by docket identification number EPA-HQ-OPP-2010-0425, by one of the methods listed in the Federal Register Notice. Comments must be received on or before July 16, 2010.

**Contact:** Marianne Lewis, Registration Division (7505), Office of Pesticide Programs, telephone number: (703) 3088043; e-mail address: lewis.marianne@epa.gov.

## **7) Pesticides; Availability of Updated Schedule for Registration Review**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34115-34117

<http://edocket.access.gpo.gov/2010/2010-14517.htm>

**Purpose:** EPA is announcing the availability of an updated schedule for the pesticide registration review program, the periodic review of all registered pesticides mandated by section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act. The updated schedule provides the timetable for opening dockets for the next 4 years of the registration review program - FY 2010 to 2013 - and includes information on the FY 2007 through FY 2009 registration review cases.

**Chemical(s):** organophosphate and carbamate; pyrethroids, pyrethrins, and synergists group\*\*

**Comments:** EPA has established a docket for this action under docket identification number EPA-HQ-OPP-2010-0030.

**Contact:** Kevin Costello, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs; telephone number: (703) 3055026; fax number: (703) 3088090; e-mail address: costello.kevin@epa.gov.

## **8) Product Cancellation Order for Certain Pesticide Registrations; Correction**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34117

<http://edocket.access.gpo.gov/2010/2010-14519.htm>

**Purpose:** EPA issued a notice in the Federal Register of May 11, 2010, concerning the final cancellation of certain pesticide product registrations. This document is being issued to correct an error in company contact information.

**Chemical(s):** various\*

**Comments:** EPA has established a docket for this action under docket identification number EPA-HQ-OPP-2009-1017.

**Contact:** Maia Tatinclaux, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, telephone number: (703) 3470123; e-mail address: tatinclaux.maia@epa.gov.

## **9) Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34117-34126

<http://edocket.access.gpo.gov/2010/2010-14329.htm>

**Purpose:** In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw their requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

**Chemical(s):** various\*

**Comments:** Submit your comments, identified by docket identification number EPA-HQ-OPP-2010-0014, by one of the methods listed in the Federal Register Notice. Comments must be received on or before December 13, 2010.

**Contact:** Maia Tatinclaux, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, telephone number: (703) 3470123; e-mail address: [tatinclaux.maia@epa.gov](mailto:tatinclaux.maia@epa.gov).

#### **10) Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations**

**Date of publication:** June 16, 2010

**Citation:** Volume 75, Number 115; Page 34117-34126

<http://edocket.access.gpo.gov/2010/2010-14329.htm>

**Purpose:** In accordance with section 6(f) (1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw their requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

**Chemical(s):** various\*

**Comments:** Submit your comments, identified by docket identification number EPA-HQ-OPP-2010-0014, by one of the methods listed in the Federal Register Notice. Comments must be received on or before December 13, 2010

**Contact:** Maia Tatinclaux, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, telephone number: (703) 3470123; e-mail address: [tatinclaux.maia@epa.gov](mailto:tatinclaux.maia@epa.gov).

#### **11) Pesticides; Draft Guidance for Pesticide Registrants on False or Misleading Pesticide Product Brand Names; Extension of Comment Period**

**Date of publication:** June 17, 2010

**Citation:** Volume 75, Number 116; Page 34448

<http://edocket.access.gpo.gov/2010/2010-14656.htm>

**Purpose:** EPA issued a notice in the Federal Register of May 19, 2010, announcing the availability of and seeking public comment on a draft Pesticide Registration Notice (PR Notice) entitled "False or Misleading Pesticide Product Brand Names." This document extends the comment period for 60 days, from June 18, 2010, to August 17, 2010.

**Chemical(s):** N/A

**Comments:** Submit your comments, identified by docket identification number EPA-HQ-OPP-2010-0282, must be received on or before August 17, 2010. Follow the detailed

instructions as provided under ADDRESSES in the Federal Register document of May 19, 2010.

**Contact:** Jeff Kempter, Antimicrobials Division (7510P), Office of Pesticide Programs, telephone number: (703) 305-5448; fax number: (703) 308-6467; e-mail address: kempter.carlton@epa.gov.

Mailing address for all listed staff: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460

\*For information about this pesticide and access to the documents being announced see: <http://www.epa.gov/pesticides/reregistration/status.htm>

\*\*For information about this pesticide and access to the documents being announced see: [http://www.epa.gov/oppsrrd1/registration\\_review/reg\\_review\\_status.htm](http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm)

\*\*\*\*\*

#### **4) Registration Decisions Opened for Public Comment for the Week of June 14, 2010:** **Aminocyclopyrachlor**

<http://www.epa.gov/pesticides/chemical/pesticide-registrations/aminocyclopyrachlor.html>

\*\*\*\*\*

EPA distributes its Pesticide Program Updates to external stakeholders and citizens who have expressed an interest in OPP activities and decisions. We have established an electronic listserve for people who want to keep abreast of pesticide issues and decisions. This update service is part of EPA's continuing effort to improve public access to Federal pesticide information.

For changes to our mailing list, e.g. e-mail addresses, telephone numbers etc. please send an email to [lormand.mary-jean@epa.gov](mailto:lormand.mary-jean@epa.gov)

For general questions on pesticides and pesticide poisoning prevention, contact the National Pesticide Information Center (NPIC), toll-free, at: 1-800-858-7378, by E-mail at [npic@ace.orst.edu](mailto:npic@ace.orst.edu), or, by visiting their website at: <http://npic.orst.edu>

To report an environmental violation, visit EPA's website at <http://www.epa.gov/compliance/complaints/index.html>

For information about ongoing activities in the Office of Pesticide Programs, visit our homepage at: <http://www.epa.gov/pesticides>

Or call or write us directly at Communication Services Branch, Office of Pesticide Programs (7506 P), US Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20004-2403, telephone 703-305-5017.

**Avi Garbow/DC/USEPA/US**  
Sent by: Monique Patrick

02/24/2010 11:05 AM

To Angela Huskey, Brenda Mallory, Charlotte Bertrand, Eric  
Schaaf, Jim Jones, Lisa Heinzerling

cc

bcc

Subject Rescheduled: Human Studies Settlement - OMB Interface  
(Feb 25 04:30 PM EST in Room 4045/DC-Ariel  
Rios-OGC@EPA)

**Avi Garbow/DC/USEPA/US**  
Sent by: Monique Patrick

02/22/2010 10:36 AM

To Angela Huskey, Brenda Mallory, Charlotte Bertrand, Eric  
Schaaf, Lisa Heinzerling

cc

bcc

Subject Human Studies Settlement - OMB Interface

**Meeting**

Date 02/25/2010

Time 04:30:00 PM to 05:30:00 PM

Chair Avi Garbow

Invitees

Required Angela Huskey; Brenda Mallory; Charlotte Bertrand; Eric Schaaf; Jim Jones;  
Lisa Heinzerling

Optional

FYI

Location 4045 AR

**Paul Anastas/DC/USEPA/US**

03/04/2010 12:14 PM

To Bob Sussman

cc Bob Perciasepe, Lisa Heinzerling, Richard Windsor, Scott  
Fulton

bcc

Subject Re: Human Studies

Bob:

yes, I view this as an important issue and will be moving ahead with it. It is not an isolated discreet issue and so I am taking the time needed to understand the cross-program activities and implications. While the overall strategy will not be developed immediately due to its complexity, we will be acting quickly to begin to address this issue.

PTA

Bob Sussman

Paul -- thanks for the time you took to w...

03/04/2010 10:05:43 AM

From: Bob Sussman/DC/USEPA/US  
To: Paul Anastas/DC/USEPA/US@EPA  
Cc: Richard Windsor/DC/USEPA/US@EPA, Bob Perciasepe/DC/USEPA/US@EPA, Scott  
Fulton/DC/USEPA/US@EPA, Lisa Heinzerling/DC/USEPA/US@EPA  
Date: 03/04/2010 10:05 AM  
Subject: Human Studies

---

Paul -- thanks for the time you took to work through the settlement language for the human studies litigation. And also thanks for being accommodating and allowing the settlement to move forward. As I've indicated to the Administrator and we've discussed, the larger challenge is to make sure that our policies on human subjects testing are well-aligned and consistent across the agency. This is where you can play a critical role in your Science Advisor capacity. I hope you'll pick up this challenge and bring some recommendations to the Administrator. Let us know how we can help. Thanks again!

Robert M. Sussman  
Senior Policy Counsel to the Administrator  
Office of the Administrator  
US Environmental Protection Agency

**Peter Caulkins/DC/USEPA/US**  
01/02/2010 03:28 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**Philip Ross/DC/USEPA/US**

12/27/2009 02:33 AM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**Philip Ross/DC/USEPA/US**

11/09/2009 04:27 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies settlement

**Philip Ross/DC/USEPA/US**

10/20/2009 09:50 AM

To Angela Huskey

cc

bcc

Subject Declined: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

Philip Ross/DC/USEPA/US

11/10/2009 09:14 AM

To Angela Huskey

cc

bcc

Subject Re: Update Requested: Discuss human studies settlement

Attorney Client Communication  
Attorney Work Product  
Deliberative  
Privileged and Confidential  
Do Not Release

Thanks. What's the specific focus for the meeting?

Philip J. Ross  
United States Environmental Protection Agency  
Office of General Counsel  
Pesticides and Toxic Substances Law Office  
202-564-5637

Angela Huskey 11.30-12 on Thursday. \*\*\*\*\* 11/10/2009 09:01:54 AM

From: Angela Huskey/DC/USEPA/US  
To: Philip Ross/DC/USEPA/US@EPA  
Date: 11/10/2009 09:01 AM  
Subject: Re: Update Requested: Discuss human studies settlement

11.30-12 on Thursday.

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

Philip Ross Update Requested: Discuss human studi... 11/09/2009 04:28:53 PM

**Update Requested: Discuss human studies settlement**

**Thu 11/12/2009 11:30 AM - 12:00 PM**

Location: Brenda's office

**Philip Ross** Update Requested

When is this meeting intended to be held? With the scheduling and then all the subsequent reschdulings, I'm not sure my calendar reflects the correct day and time?

Required: Brenda Mallory/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Philip Ross/DC/USEPA/US@EPA  
Optional: Robert Perlis/DC/USEPA/US@EPA

#### Description

**Philip Ross/DC/USEPA/US**

10/17/2006 02:06 PM

To Angela Huskey

cc

bcc

Subject Tentative: Discuss response for Human Studies litigation

**Philip Ross/DC/USEPA/US**

11/09/2009 04:28 PM

To Angela Huskey

cc

bcc

Subject Update Requested: Discuss human studies settlement

**Philip Ross/DC/USEPA/US**

08/17/2009 04:11 PM

To Brenda Mallory

cc

bcc

Subject Accepted: Human Studies Settlement

**Philip Ross/DC/USEPA/US**

05/27/2009 11:35 AM

To Brenda Mallory

cc

bcc

Subject Accepted: Human Studies Settlement - Conference Call

**Philip Ross/DC/USEPA/US**

06/02/2009 10:09 AM

To Brenda Mallory

cc

bcc

Subject Accepted: Human Studies Settlement Conference Call

Philip Ross/DC/USEPA/US

03/02/2006 02:03 PM

To Brenda Mallory

cc Brian Grant, Keith Matthews, OGC PTSLO

bcc

Subject Re: Fw: 3rd party Rule

Attorney Client Communication  
Attorney Work Product  
Deliberative  
Privileged and Confidential  
Do Not Release

FYI--cut and pasted from the NRDC website:

---

**FOR IMMEDIATE RELEASE**

**Press contact:** NRDC: Craig Noble, (415) 875-6100, or Elliott Negin, NRDC, 202-289-6868; Pesticide Action Network: Dr. Margaret Reeves, (415) 981-6205 ext 319; Earthjustice: Jan Hasselman, (206) 343-7340 ext 25

If you are not a member of the press, please write to us at [nrdcinfo@nrdc.org](mailto:nrdcinfo@nrdc.org) or see our [contact page](#).

**GROUPS SUE EPA FOR APPROVING UNETHICAL, ILLEGAL HUMAN PESTICIDE TESTING**

SAN FRANCISCO (February 23, 2006) -- A new Environmental Protection Agency rule will turn more Americans into lab rats for industry pesticide tests, according to lawsuits filed today by a coalition of health and environmental advocates, farmworkers and doctors. The groups contend that the agency's human testing rule violates a law passed by Congress in 2005 mandating strict ethical and scientific protections for pesticide testing on humans.

"EPA's rule allows pesticide companies to use intentional tests on humans to justify weaker restrictions on pesticides," said Dr. Margaret Reeves, a senior staff scientist with Pesticide Action Network.

Although the rule prohibits some kinds of testing and limits others, it is riddled with loopholes that undermine its effectiveness and ultimately encourage more human testing, the coalition groups said. The rule also fails to ensure that pesticide testing on human subjects meets the strictest scientific and ethical standards recommended by a 2004 National Academy of Sciences report and outlined in the Nuremberg Code after World War II.

The chemical industry concedes that its goal is to weaken safety standards by circumventing the margin of safety the EPA uses to estimate a safe human exposure level based on animal studies. As a result of the agency's illegal rule, the EPA will rely on unethical and unscientific human pesticide tests to weaken regulatory standards, the groups charge.

There have been serious ethical and scientific problems with such tests in the past. For

example, a company told participants in one test they were eating vitamins, not toxic pesticides. In many other tests, companies have not provided any long-term follow-up to protect participants' health.

The Clinton administration banned the EPA from relying on the results of such tests because of their questionable scientific and ethical integrity. The Bush administration at first ratified the Clinton-era moratorium, but then lifted the ban. Congress reimposed it in 2005, pending finalization of stricter rules.

"The EPA's rule puts pesticide companies' profits ahead of human health and scientific integrity," said Dr. Robert Gould, a pathologist and president of San Francisco Bay Area Physicians for Social Responsibility. "Pesticide companies should not be allowed to take advantage of vulnerable populations by enticing people to serve as human laboratory rats."

Erik Olson, a senior attorney with the Natural Resources Defense Council, agreed. "The industry's human pesticide tests are unscientific and unethical," Olson said. "Their record of abuse is appalling, yet the EPA disregards Congress' order to crack down on this abhorrent practice."

"Unethical testing of pesticides on humans is wrong and has to be stopped," said Jan Hasselman, an attorney with Earthjustice representing the groups in the lawsuit. "EPA's rule ignores Congress and allows unethical human tests to be used to weaken pesticide regulations."

The lawsuits were filed simultaneously in the Second Circuit Court of Appeals in New York City and the Ninth Circuit Court of Appeals in San Francisco. The groups filing lawsuits today include Pesticide Action Network North America, Pineros y Campesinos Unidos del Noroeste (Northwest Treeplanters and Farmworkers United), San Francisco Bay Area Physicians for Social Responsibility, and Natural Resources Defense Council. They are represented by attorneys with Earthjustice and NRDC.

The Natural Resources Defense Council is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has 1.2 million members and online activists nationwide, served from offices in New York, Washington, Los Angeles and San Francisco.

Philip J. Ross  
United States Environmental Protection Agency  
Office of General Counsel  
Pesticides and Toxic Substances Law Office  
202-564-5637

Brenda Mallory/DC/USEPA/US

**Brenda  
Mallory/DC/USEPA/US**  
03/02/2006 01:19 PM


To Keith Matthews/DC/USEPA/US@EPA  
cc Brian Grant/DC/USEPA/US@EPA, OGC PTSLO, Philip  
Ross/DC/USEPA/US@EPA  
Subject Re: Fw: 3rd party Rule 📎

I received a copy of the 9th Circuit Petition and it is in the Circuit Court. There may be something in District Court as well but this definitely said Circuit Court.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov  
Keith Matthews/DC/USEPA/US

**Keith  
Matthews/DC/USEPA/US**


03/02/2006 01:08 PM

To Philip Ross/DC/USEPA/US@EPA  
cc Brian Grant/DC/USEPA/US@EPA, OGC PTSLO  
Subject Re: Fw: 3rd party Rule 

We have recent intelligence indicating that the 9th Circuit suit is in District Court. Mary Grady is still attempting to run down a complaint for us.  
Philip Ross/DC/USEPA/US

**Philip Ross/DC/USEPA/US**

03/02/2006 12:56 PM

To Brian Grant/DC/USEPA/US@EPA  
cc OGC PTSLO  
Subject Re: Fw: 3rd party Rule 

Attorney Client Communication  
Attorney Work Product  
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Do Not Release

Could the inquiry possibly relate to the Human Subjects final rule which covers, among other things, third-party human subject studies?

If so, the answer is yes. Keith characterized the pending round of litigation in the following manner: "NRDC and other environmental organizations are purported to have filed petitions for review of EPA's final human testing rule in both the 2d Second Circuit and the 9th Circuit (NRDC has shared a copy of its 2d Circuit petition; the petition in the 9th Circuit has been reported in the media)."

Philip J. Ross  
United States Environmental Protection Agency  
Office of General Counsel  
Pesticides and Toxic Substances Law Office  
202-564-5637

Brian Grant/DC/USEPA/US

**Brian Grant/DC/USEPA/US**

03/02/2006 12:14 PM

To OGC PTSLO  
cc  
Subject Fw: 3rd party Rule

maybe i should, but i have no idea what the third party rule is. if you know, could you please let me know so i can get back to susie? thanks.

Brian Grant  
Office of General Counsel (2333 A)  
U.S. EPA  
phone: (202) 564-5503  
fax: (202) 564-5644

----- Forwarded by Brian Grant/DC/USEPA/US on 03/02/2006 12:13 PM -----

**Susan Hazen/DC/USEPA/US**

03/02/2006 08:58 AM

To Brian Grant/DC/USEPA/US@EPA  
cc  
Subject 3rd party Rule

I have been asked if we have been sued regarding the "3rd party Rule"

Any info?

Susan B. Hazen,  
Acting Assistant Administrator  
Office of Prevention, Pesticides and Toxic Substances  
(Phone) 202-564-2910 (fax) 202-564-0512

**Robert Perlis/DC/USEPA/US**

11/09/2009 05:23 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies settlement

**Robert Perlis/DC/USEPA/US**  
01/19/2010 10:23 AM

To Scott Fulton  
cc  
bcc  
Subject Accepted: Discussion on Human Studies Settlement

**Robert Perlis/DC/USEPA/US**

01/21/2010 05:19 PM

To Scott Fulton

cc

bcc

Subject Accepted: Discussion on Human Studies Settlement

**Robert Perlis/DC/USEPA/US**

01/28/2010 02:50 PM

To Scott Fulton

cc

bcc

Subject Accepted: Discussion on Human Studies Settlement

Robin Spriggs/DC/USEPA/US

11/16/2009 03:33 PM

To Angela Huskey

cc Brenda Mallory

bcc

Subject human studies - Ok, I just moved it again to tomorrow at 3pm

Robin U. Spriggs  
Executive Assistant  
Environmental Protection Agency  
Office of the General Counsel, Rm. 4014 ARN  
Washington, DC 20460  
Phone: 202/564-8040  
FAX: 202/564-1778

Angela Huskey Robin, Sorry to mess up the scheduling... 11/16/2009 03:15:02 PM

From: Angela Huskey/DC/USEPA/US  
To: Robin Spriggs/DC/USEPA/US@EPA  
Cc: Brenda Mallory/DC/USEPA/US@EPA  
Date: 11/16/2009 03:15 PM  
Subject: Re: human studies - Ok, I went ahead and moved the meeting to now start at 2pm on Wed. for now

Robin,

Sorry to mess up the scheduling, but the 3 pm time slot for tomorrow works better for me, since I have a briefing at Potomac Yards from 1-2 on Wednesday (and wouldn't be able to get back for a meeting until 2.30.) Is it still possible to hold the meeting at 3 tomorrow?

Thanks,  
Angela

\*\*\*\*\*

Angela M.D. Huskey  
Office of General Counsel, Pesticides and Toxic Substances Law Office  
Mail Code 2333A  
Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

Room 7426HH - Ariel Rios North  
Phone: (202) 564-2892  
Fax: (202) 564-5644

Robin Spriggs Robin U. Spriggs Executive Assistant 11/16/2009 02:19:24 PM

From: Robin Spriggs/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Cc: Angela Huskey/DC/USEPA/US@EPA, Avi Garbow/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Khisa Lee/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA  
Date: 11/16/2009 02:19 PM  
Subject: Re: human studies - Ok, I went ahead and moved the meeting to now start at 2pm on Wed. for now

Robin U. Spriggs  
Executive Assistant  
Environmental Protection Agency  
Office of the General Counsel, Rm. 4014 ARN  
Washington, DC 20460  
Phone: 202/564-8040  
FAX: 202/564-1778

---

Brenda Mallory      Yes, this is our meeting. Let me consul...      11/16/2009 01:51:27 PM

From: Brenda Mallory/DC/USEPA/US  
To: Avi Garbow/DC/USEPA/US@EPA  
Cc: Angela Huskey/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA, Khisa Lee/DC/USEPA/US@EPA, Robin Spriggs/DC/USEPA/US@EPA  
Date: 11/16/2009 01:51 PM  
Subject: Re: human studies

---

Yes, this is our meeting. Let me consult with the team. We do need to talk to you this week so we'll see what we can do with other meetings we have. If it is tomorrow, we won't be able to get materials to you today. I'll circle back.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

---

Avi Garbow      Brenda, I've got a meeting at 3 Wed. re...      11/16/2009 01:43:06 PM

From: Avi Garbow/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Date: 11/16/2009 01:43 PM  
Subject: human studies

---

Brenda,

I've got a meeting at 3 Wed. re: human studies litigation. This may be a briefing that your shop set up for me (my calendar entry doesn't tell me who is involved). I now have a conflict then. Can we either move that briefing to 3 tomorrow (Tues.) or else to 2 on Wed.?

Avi Garbow  
Deputy General Counsel  
U.S. Environmental Protection Agency  
(202) 564-1917

**Robin Spriggs/DC/USEPA/US**  
11/17/2009 10:50 AM

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject HEADS UP - Human Studies Litigation Mtg.

Avi has another meeting at OMB and would like to start the Human Studies meeting a little later would  
4:30 today work for you guys?

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Human Studies litigation

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Human Studies litigation

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Human Studies litigation

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Human Studies litigation

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Human Studies litigation

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Human Studies litigation

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

11/16/2009 03:31 PM

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Rescheduled: Human Studies litigation (Nov 17 03:00 PM  
EST in 4407a)

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

11/17/2009 10:48 AM

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Rescheduled: Human Studies litigation (Nov 17 04:30 PM  
EST in 4407a)

**Avi Garbow/DC/USEPA/US**  
Sent by: Robin Spriggs

11/16/2009 02:17 PM

To Angela Huskey, Brenda Mallory, Jonathan Fleuchaus, Keith  
Matthews

cc

bcc

Subject Rescheduled: Human Studies litigation (Nov 18 02:00 PM  
EST in 4407a)

Robin Spriggs/DC/USEPA/US

11/16/2009 02:19 PM

To Brenda Mallory

cc Angela Huskey, Avi Garbow, Keith Matthews, Khisa Lee, Robert Perlis

bcc

Subject Re: human studies - Ok, I went ahead and moved the meeting to now start at 2pm on Wed. for now

Robin U. Spriggs  
Executive Assistant  
Environmental Protection Agency  
Office of the General Counsel, Rm. 4014 ARN  
Washington, DC 20460  
Phone: 202/564-8040  
FAX: 202/564-1778

Brenda Mallory Yes, this is our meeting. Let me consul... 11/16/2009 01:51:27 PM

From: Brenda Mallory/DC/USEPA/US  
To: Avi Garbow/DC/USEPA/US@EPA  
Cc: Angela Huskey/DC/USEPA/US@EPA, Keith Matthews/DC/USEPA/US@EPA, Robert Perlis/DC/USEPA/US@EPA, Khisa Lee/DC/USEPA/US@EPA, Robin Spriggs/DC/USEPA/US@EPA  
Date: 11/16/2009 01:51 PM  
Subject: Re: human studies

Yes, this is our meeting. Let me consult with the team. We do need to talk to you this week so we'll see what we can do with other meetings we have. If it is tomorrow, we won't be able to get materials to you today. I'll circle back.

Brenda Mallory  
Associate General Counsel, Pesticide and Toxic Substances Law Office  
U.S. Environmental Protection Agency  
(202) 564-0633 (telephone)  
(202) 564- 5644 (fax)  
mallory.brenda@epa.gov

Avi Garbow Brenda, I've got a meeting at 3 Wed. re... 11/16/2009 01:43:06 PM

From: Avi Garbow/DC/USEPA/US  
To: Brenda Mallory/DC/USEPA/US@EPA  
Date: 11/16/2009 01:43 PM  
Subject: human studies

Brenda,

I've got a meeting at 3 Wed. re: human studies litigation. This may be a briefing that your shop set up for me (my calendar entry doesn't tell me who is involved). I now have a conflict then. Can we either move that briefing to 3 tomorrow (Tues.) or else to 2 on Wed.?

Avi Garbow  
Deputy General Counsel

U.S. Environmental Protection Agency  
(202) 564-1917

**Scott Fulton/DC/USEPA/US**  
03/04/2010 12:48 AM

To "Angela Huskey", "Brenda Mallory"  
cc "Steve Owens"  
bcc  
Subject Human Studies Settlement

Hi Folks - Green light to represent that we have an agreement in principle. Thanks for all the great work!  
Scott

Steven  
Bradbury/DC/USEPA/US  
06/17/2010 12:29 PM

To Debby Sisco  
cc angulo.karen, Margie Fehrenbach  
bcc  
Subject Re: Fw: settlement agreement for human studies

thanks. looks good

Debby Sisco      [Steve This OPP Update and a similar I...](#)      06/17/2010 09:57:41 AM

From: Debby Sisco/DC/USEPA/US  
To: Steven Bradbury  
Cc: Margie Fehrenbach, Karen Angulo  
Date: 06/17/2010 09:57 AM  
Subject: Fw: settlement agreement for human studies

---

Steve

This OPP Update and a similar Internal Alert have been approved by Bill Jordan. The settlement agreement was filed with the courts yesterday, so it may be in the news today. We have already had at least one inquiry. Web updates will be added as soon as they are ready. Update will go out tomorrow. It all looks fine to me.

Debby

## **OPP Update for publication ASAP**

### **EPA Settles Lawsuit over Its 2006 Human Subjects Protections Rule**

EPA has settled a lawsuit over its 2006 regulation that established protections for subjects of human research. Under the settlement, EPA agrees to propose amendments to the rule consistent with language negotiated with groups who challenged that rule. The proposed changes will formalize many current procedures that EPA has been following as it implemented the 2006 rule and address the three principal areas identified by the petitioners: the scope of the rule, its consistency with the 2004 National Academy of Science recommendations, and its consistency with the Nuremberg Code.

As required by [the Human Subjects Protections Rule settlement](#), EPA will publish the proposed amendments in a *Federal Register* notice before January 16, 2011, and open a public comment period at the same time. The amendments will be finalized by December 16, 2011.

Debby Sisco  
Office of Pesticide Programs  
Ethics Officer and Special Assistant to the Director  
Room 12244 Potomac Yard South --- (703 308-8121)  
----- Forwarded by Debby Sisco/DC/USEPA/US on 06/17/2010 09:52 AM -----

From: Quentin Borges-Silva/DC/USEPA/US  
To: Debby Sisco/DC/USEPA/US@EPA  
Cc: Margie Fehrenbach/DC/USEPA/US@EPA, Karen Angulo/DC/USEPA/US@EPA, Claire Gesalman/DC/USEPA/US@EPA  
Date: 06/16/2010 04:53 PM  
Subject: Fw: settlement agreement for human studies

---

Hi.

Bill Jordan and Claire have reviewed and approved the attached commstrat, internal alert, opp update, and web updates below. The settlement agreement was filed with the courts today, so it may be in the news tomorrow. Once I have your approval, the internal alert will go out after the web team makes all of the web updates; the opp update will go out on Friday.

Thanks,

Quentin Borges-Silva  
Field and External Affairs Division  
EPA's Pesticide Program  
703-308-0395  
Visit <http://www.epa.gov/pesticides>

[attachment "COMM STRAT -- human studies settlement 6-10-10.doc" deleted by Steven Bradbury/DC/USEPA/US] [attachment "Human Studies Web updates.doc" deleted by Steven Bradbury/DC/USEPA/US] [attachment "OPP Update.human studies suit.doc" deleted by Steven Bradbury/DC/USEPA/US] [attachment "DRAFT Internal Alert.human studies.6.16.10.doc" deleted by Steven Bradbury/DC/USEPA/US]

----- Forwarded by Quentin Borges-Silva/DC/USEPA/US on 06/16/2010 04:47 PM -----

From: William Jordan/DC/USEPA/US  
To: Quentin Borges-Silva/DC/USEPA/US@EPA  
Date: 06/16/2010 04:33 PM  
Subject: Re: Fw: settlement agreement for human studies

---

I concur.

Thanks,

Bill

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

Quentin Borges-Silva	<a href="#">Thanks, Bill. Please review the at...</a>	06/16/2010 03:14:18 PM
William Jordan	<a href="#">Here is an unsigned copy. Bill</a>	06/16/2010 02:04:02 PM



**William Jordan/DC/USEPA/US**  
10/14/2009 05:14 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss human studies rule settlement agreement;  
impact on timelines for DDVP, aldicarb, and amitraz

**William Jordan/DC/USEPA/US**  
12/22/2009 04:04 PM

To Angela Huskey

cc

bcc

Subject Accepted: Discuss options for aldicarb and amitraz in human studies settlement

**William Jordan/DC/USEPA/US**  
10/17/2006 12:08 PM

To Angela Huskey  
cc  
bcc  
Subject Accepted: Discuss response for Human Studies litigation

William Jordan/DC/USEPA/US  
03/15/2010 08:15 AM

To Brenda Mallory, Angela Huskey, Jonathan Fleuchaus, Robert Perlis  
cc  
bcc  
Subject Fw: follow-up Qs Peter had on some fo the pesticide Qs and As for Wednesday's hearing

Brenda et al. --

Would you like to answer the follow-up question about the HS settlement or would you prefer that I write up something?

Thanks,

Bill

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

----- Forwarded by William Jordan/DC/USEPA/US on 03/15/2010 08:13 AM -----

From: Margie Fehrenbach/DC/USEPA/US  
To: Kathy Seikel/DC/USEPA/US@EPA  
Cc: gesalman.claire@epa.gov, sisco.debby@epa.gov, jordan.william@epa.gov  
Date: 03/14/2010 11:47 PM  
Subject: Re: follow-up Qs Peter had on some fo the pesticide Qs and As for Wednesday's hearing

---

Kathy--I will take the easy one --

Pesticide Registration (PR) Notices are issued by the Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies, procedures and regulatory decisions.

I am copying Bill Jordan regarding the human studies question. I think Debby can find the worker protection standards status in the Scout database.

Margie Fehrenbach  
Office of Pesticide Programs (7501-P)  
US Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
703/308-4775 Phone  
703/308-4776 Fax  
202/413-5414 Cell

Street Address: 2777 Crystal Drive  
1 Potomac Yard S, Rm 12641, Arlington, VA

-----Kathy Seikel/DC/USEPA/US wrote: -----

To: Margie Fehrenbach/DC/USEPA/US@EPA, Debby Sisco/DC/USEPA/US@EPA, Claire Gesalman/DC/USEPA/US@EPA  
From: Kathy Seikel/DC/USEPA/US  
Date: 03/14/2010 10:21PM  
cc: Douglas Parsons/DC/USEPA/US@EPA  
Subject: follow-up Qs Peter had on some fo the pesticide Qs and As for Wednesday's hearing

Hi, everyone -

Peter Grevatt had a few follow-up questions on the pesticides Qs and As I provided him for this Wednesday's children's health before SEPW. Can you provide quick response to the three questions below?

(I should know what PR notice is but don't....I think it's peculiar to the pesticide programs,,,,,,nor sure i any other programs use this term). Thanks. **I need these answers before noon on Monday .**

- What is the expected timing on the settlement on the human studies rule and what are the expected dates for the rule? Was there ever follow-up with Grant Cope\* in response to his request for a briefing on the status of the rule?.
- What is the status of our action on the pesticides worker protection standards?
- What is a pesticide PR notice?

\* Grant Cope is SEPW Majority Counsel

Kathy Seikel  
Environmental Protection Agency  
Office of the Administrator  
Office of Children's Health Protection (1107A)  
1200 Penna. Ave., NW  
Washington, DC 20460  
202-564-0457 (ph)  
202-564-2733 (fax)  
visit: [www.epa.gov/children](http://www.epa.gov/children)

**William Jordan/DC/USEPA/US**

06/01/2010 04:29 PM

To Douglas Parsons

cc "Robert Perlis"

bcc

Subject Re: HS litigation

Jon Fleuchaus told me that DOJ asked for and got a stay until 6-16. So not until then.

Bill

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

Douglas Parsons

[Hey bill or Bob---When will the human...](#)

06/01/2010 03:50:42 PM

From: Douglas Parsons/DC/USEPA/US  
To: "Robert Perlis" <Perlis.Robert@epamail.epa.gov>, "William Jordan" <Jordan.William@epamail.epa.gov>  
Date: 06/01/2010 03:50 PM  
Subject: HS litigation

---

Hey bill or Bob---When will the human studies litigation be filed w the court? Thanks, doug

William Jordan/DC/USEPA/US  
02/18/2010 01:02 PM

To Jay Ellenberger  
cc  
bcc  
Subject Re: cab to the hill

Thanks. I can't go; I need to attend a meeting with Mr. Sussman on Human Studies litigation.

Good luck,

**Bill**

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

Jay Ellenberger	cathryn, rick k. and i are meeting at 2 d...	02/18/2010 12:51:50 PM
-----------------	--	------------------------

From: Jay Ellenberger/DC/USEPA/US  
To: William Jordan/DC/USEPA/US@EPA  
Date: 02/18/2010 12:51 PM  
Subject: cab to the hill

---

cathryn, rick k. and i are meeting at 2 down in the lobby. will you join us?

Jay

Jay Ellenberger, Deputy Director  
Field and External Affairs Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
703/305-7099  
Visit <http://www.epa.gov/pesticides>

William Jordan/DC/USEPA/US  
02/24/2010 01:53 PM

To Joyce Crowley  
cc  
bcc  
Subject Re: Fw: Forwarded meeting Notice from Avi Garbow:  
Rescheduled: Human Studies Settlement - OMB Interface  
(Feb 25 04:30 PM EST in Room 4045/DC-Ariel  
Rios-OGC@EPA)

I have added this to my calendar and will attend.

I note that the meeting starts at 4:30 and your message indicates Jim's prep session ends at 4:00 PM. That does not seem like a conflict to me, unless the prep session runs significantly longer than it is scheduled to last.

Thanks,

Bill

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

Joyce Crowley Bill-- Jim has a hearing prep meeting sc... 02/24/2010 01:13:39 PM

From: Joyce Crowley/DC/USEPA/US  
To: William Jordan/DC/USEPA/US@EPA  
Date: 02/24/2010 01:13 PM  
Subject: Fw: Forwarded meeting Notice from Avi Garbow: Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)

Bill--

Jim has a hearing prep meeting scheduled from 3:00 - 4:00 on Thursday, Feb 25 and he would like for you to attend this meeting for him until he arrives. Call or email me if you can't make it.

Joyce

----- Forwarded by Joyce Crowley/DC/USEPA/US on 02/24/2010 12:57 PM -----


From: Jim Jones/DC/USEPA/US  
To: Joyce Crowley/DC/USEPA/US, Harriett Haymon/DC/USEPA/US, Denise Adams/DC/USEPA/US, Lynda Garland/DC/USEPA/US  
Date: 02/24/2010 11:05 AM  
Subject: Forwarded meeting Notice from Avi Garbow: Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)

A Meeting Request for Jim Jones requires your attention.

The subject of the notice is

Rescheduled: Human Studies Settlement - OMB Interface (Feb 25 04:30 PM EST in Room 4045/DC-Ariel Rios-OGC@EPA)

The meeting is chaired by Avi Garbow

Please process this request -> 

William Jordan/DC/USEPA/US  
11/10/2010 08:09 AM

To Kelly Sherman, Laura Parsons, Angela Huskey, Jonathan  
Fleuchaus  
cc  
bcc  
Subject Fw: Settlement agreement

FYI

Bill

William L. Jordan  
Senior Policy Adviser  
Office of Pesticide Programs -- Mail code 7501P  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
(703) 305-1049 (voice)  
(703) 308-4776 (fax)

----- Forwarded by William Jordan/DC/USEPA/US on 11/10/2010 08:08 AM -----

From: John Carley/DC/USEPA/US  
To: William Jordan/DC/USEPA/US@EPA  
Date: 11/09/2010 04:51 PM  
Subject: Fw: Settlement agreement

---

Here's my email exchange with Curt Lunchick shortly after we posted the settlement agreement to the web.

There's another message I'll send you in a minute in which he reports on the reaction of the AHETF to this information from me.

Quidquid latine dictum sit altum viderunt

John M. Carley  
Program Analyst  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
tel: 703 305-7019  
fax: 703 308-4776

----- Forwarded by John Carley/DC/USEPA/US on 11/09/2010 04:49 PM -----

From: John Carley/DC/USEPA/US  
To: Curt Lunchick <curt.lunchick@bayercropscience.com>  
Date: 06/19/2010 07:05 PM  
Subject: Re: Settlement agreement

---

Remember, first, that the agreement calls for us to propose amendments to the rule substantially consistent with the negotiated language. Depending on what happens in the notice and comment rulemaking process, the final rule may end up looking more or less like the proposal. But the 2006 rule remains in effect until something different is promulgated as a final rule.

There is some concern in other parts of EPA that their operations could be adversely impacted by the negotiated changes in scope and applicability. These are complicated, and all that complication is intended to close a perceived loophole in the current rule. Petitioners argued that since the 2006 rule

applies only to research intended for consideration under FIFRA and FFDCA, it would allow unethical pesticide human studies to be conducted and submitted to EPA under other statutes, and to be relied on by EPA under other statutes, while entirely escaping regulation. We know of no studies which would be within the scope of the negotiated proposal language but not within the scope of the 2006 rule, but we acknowledge that it is conceivable there might be some. We tried our best in the drafting to minimize the possibility of any inadvertent burdens on our colleagues in other programs resulting from the language changes.

I share your view that the negotiated language would have negligible impact on exposure studies. Notwithstanding the press releases you may have seen, I don't think it's correct to characterize these changes as making the rule stricter. The changes in the language of the decision rules in subpart Q would not, in our view, have led to any outcomes different from those that have resulted from applying the 2006 rule. The new language in subpart P listing topics EPA must consider in its reviews of proposed research does not define decision criteria, but simply lists things for us to think about. This new language, adapted from the 2004 NAS recommendations, doesn't include anything we haven't already been addressing, but it does formalize in regulation the scope of the reviews we've been conducting over the past several years. Because the wording is a little different, we plan to revise the "framework" we've been using for our protocol reviews to make it obvious to any reader that we are, indeed, thinking about all these things. Some revisions in the organization and section headings for reviews of completed studies will probably also be needed, again to make our compliance obvious.

My own view is that the negotiated language changes would have very little effect, if any, either on the procedures we've worked out in the course of implementing the 2006 rule or on the substantive outcomes of EPA and HSRB reviews.

Quidquid latine dictum sit altum viderunt

John M. Carley  
Program Analyst  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
tel: 703 305-7019  
fax: 703 308-4776

Curt Lunchick

[John, Obviously the settlement agreem...](#)

06/18/2010 10:13:17 PM

---

From: Curt Lunchick <curt.lunchick@bayercropscience.com>  
To: John Carley/DC/USEPA/US@EPA  
Date: 06/18/2010 10:13 PM  
Subject: Settlement agreement

---

John,

Obviously the settlement agreement has people's shorts twisted. I have read the thing and here is my take. Want to see if it is similar to yours or whether I missed something.

First, the proposed changes tightened restrictions on vulnerable populations.

Second, the proposed changes raise the hurdle for human clinical (tox) trials by requiring consideration of existing animal data or whether observational human data can address the scientific question.

I tend to conclude that the proposed changes would have minimal impact on worker intentional dosing studies. We already address many of the issues raised such as whether there are existing data that could address the issue and we spent two years developing study participant recruitment methods that provide a sample that is sufficiently representative for the purposes for which EPA intends to use the data. Is this

the position that you and Bill would take?

If I want to be paranoid and believe in malicious individuals who do not want to see worker exposure studies, I could also see EPA requiring observational studies and requiring large samples to address population representativeness. I assume the previous paragraph is more in line with the Agency's view. correct?

Cheers / Mit freundlichen Grüßen / Cordialement

**Curt Lunchick**



**Bayer CropScience**

**Bayer CropScience**

USA - Product Safety Manage

Telefon : +1 919-549-2986

Telefax: +1 919-549-2924

E-Mail [curt.lunchick@bayer.com](mailto:curt.lunchick@bayer.com)

URL <http://www.bayercropscience.com>

Create your personal signature for your mailing - [CLICK HERE](#) -

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

---

**William Jordan/DC/USEPA/US**

To

cc

bcc

Subject Human Studies Settlement: OMB Interface

**Meeting**

Date 02/25/2010

Time 04:30:00 PM to 05:30:00 PM

Chair William Jordan

Invitees

Required

Optional

FYI

Location 4045 Ariel Rios

"Aitken, Steven D."  
<Steven\_D.\_Aitken@omb.eop.  
gov>

03/27/2010 08:34 AM

To Brenda Mallory

cc

bcc

Subject Out of Office AutoReply: EPA Settlement Agreement in  
Human Studies litigation - status?

I am out of the office on Monday and Tuesday, March 29-30. If you need to reach an attorney in OMB Counsel's office on those days, please contact Kimberley Luczynski at 202-395-7870. I will be back in the office on Wednesday, March 31.

Have a Happy New Year.

"Greenberg, Alan (ENRD)"  
<AGreenbe@ENRD.USDOJ.G  
OV>

08/23/2006 04:50 PM

To: Angela Huskey

cc

bcc

Subject: RE: Inside EPA article about Human studies litigation

I am not a subscriber, so I cannot access the document. Alan

-----Original Message-----

From: Huskey.Angela@epamail.epa.gov

[mailto:Huskey.Angela@epamail.epa.gov]

Sent: Wednesday, August 23, 2006 2:41 PM

To: Matthews.Keith@epamail.epa.gov; Greenberg, Alan (ENRD)

Subject: Inside EPA article about Human studies litigation

[http://insideepa.com/secure/docnum.asp?f=epa\\_2001.ask&docnum=8222006\\_studies](http://insideepa.com/secure/docnum.asp?f=epa_2001.ask&docnum=8222006_studies)

\*\*\*\*\*

Angela M.D. Huskey

Office of General Counsel, Pesticides and Toxic Substances Law Office

Mail Code 2333A

Environmental Protection Agency

1200 Pennsylvania Ave., NW

Washington, D.C. 20460

Room 7426HH - Ariel Rios North

Phone: (202) 564-2892

Fax: (202) 564-5644

"Kymn, Christine J."  
<Christine\_J.\_Kymn@omb.eop  
.gov>

11/29/2010 05:32 PM

To Angela Hofmann

cc Jonathan Fleuchaus, Angela Huskey, Kelly Sherman,  
Charlotte Bertrand, Melissa Chun

bcc

Subject RE: Settlement Agreement in Human Studies Rule Related  
Litigation

Thanks, Angela!

-----Original Message-----

From: Hofmann.Angela@epamail.epa.gov [mailto:Hofmann.Angela@epamail.epa.gov]

Sent: Monday, November 29, 2010 5:13 PM

To: Kymn, Christine J.

Cc: fleuchaus.jonathan@epamail.epa.gov; Huskey.Angela@epamail.epa.gov;

Sherman.Kelly@epamail.epa.gov; Bertrand.Charlotte@epamail.epa.gov;

Chun.Melissa@epamail.epa.gov

Subject: Fw: Settlement Agreement in Human Studies Rule Related Litigation

Christine -

DOJ informed our attorney, Jon Fleuchaus, that OMB asked them for a copy of the settlement agreement in this case. DOJ asked us to provide the document to you. Here is a copy of the second agreement, which supersedes the one provided previously.

- Angela

(See attached file: Settlement Agreement 2d executed.pdf)

Angela Hofmann

Director of Regulatory Coordination for Chemical

Safety and Pollution Prevention (OCSPP) U.S. Environmental Protection  
Agency (EPA)

Mailcode: 7101M

1200 Pennsylvania Ave., N.W., Washington, DC 20460

(Location: EPA East Building Room 3426 A) Phone number: 202-564-0258; Fax  
number: 202-564-0263

----- Forwarded by Angela Hofmann/DC/USEPA/US on 11/29/2010 05:02 PM

-----

From: Angela Hofmann/DC/USEPA/US

To: David\_Rostker@omb.eop.gov, James\_A.\_Laity@omb.eop.gov

Cc: John Carley/DC/USEPA/US@EPA, Kelly Sherman/DC/USEPA/US@EPA,  
William Jordan/DC/USEPA/US@EPA, Charlotte  
Bertrand/DC/USEPA/US@EPA, Jonah Richmond/DC/USEPA/US@EPA

Date: 10/01/2010 02:24 PM

Subject: Settlement Agreement in Human Studies Rule Related Litigation

David -

As requested in your voicemail yesterday, here is a copy of the signed

Settlement Agreement for the Human Studies Rule. I will get back to you on availability for scheduling the introductory briefing for the interagency reviewers. I just need to confirm availability of key staff. Thanks.  
- Angela

[attachment "panna settlement agmt.pdf" deleted by Angela Hofmann/DC/USEPA/US]

Angela Hofmann  
Director of Regulatory Coordination for Chemical  
Safety and Pollution Prevention (OCSPP) U.S. Environmental Protection  
Agency (EPA)  
Mailcode: 7101M  
1200 Pennsylvania Ave., N.W., Washington, DC 20460  
(Location: EPA East Building Room 3426 A) Phone number: 202-564-0258; Fax  
number: 202-564-0263

"Kymn, Christine J."  
<Christine\_J.\_Kymn@omb.eop  
.gov>

11/29/2010 06:34 PM

To Angela Hofmann

cc Jonathan Fleuchaus, Angela Huskey, Kelly Sherman,  
Charlotte Bertrand, Melissa Chun

bcc

Subject RE: Settlement Agreement in Human Studies Rule Related  
Litigation

Hi Angela,  
Thanks again for sending. Quick question - could you please send Exhibit A,  
or does that remain unchanged from the original settlement agreement (i.e.,  
the one you sent to David in October and that went out to interagency  
reviewers)?  
Have a great evening,  
Christine

-----Original Message-----

From: Hofmann.Angela@epamail.epa.gov [mailto:Hofmann.Angela@epamail.epa.gov]  
Sent: Monday, November 29, 2010 5:13 PM  
To: Kymn, Christine J.  
Cc: fleuchaus.jonathan@epamail.epa.gov; Huskey.Angela@epamail.epa.gov;  
Sherman.Kelly@epamail.epa.gov; Bertrand.Charlotte@epamail.epa.gov;  
Chun.Melissa@epamail.epa.gov  
Subject: Fw: Settlement Agreement in Human Studies Rule Related Litigation

Christine -  
DOJ informed our attorney, Jon Fleuchaus, that OMB asked them for a copy of  
the settlement agreement in this case. DOJ asked us to provide the document  
to you. Here is a copy of the second agreement, which supersedes the one  
provided previously.  
- Angela

(See attached file: Settlement Agreement 2d executed.pdf)

Angela Hofmann  
Director of Regulatory Coordination for Chemical  
Safety and Pollution Prevention (OCSPP) U.S. Environmental Protection  
Agency (EPA)  
Mailcode: 7101M  
1200 Pennsylvania Ave., N.W., Washington, DC 20460  
(Location: EPA East Building Room 3426 A) Phone number: 202-564-0258; Fax  
number: 202-564-0263  
----- Forwarded by Angela Hofmann/DC/USEPA/US on 11/29/2010 05:02 PM  
-----

From: Angela Hofmann/DC/USEPA/US  
To: David\_Rostker@omb.eop.gov, James\_A.\_Laity@omb.eop.gov  
Cc: John Carley/DC/USEPA/US@EPA, Kelly Sherman/DC/USEPA/US@EPA,  
William Jordan/DC/USEPA/US@EPA, Charlotte  
Bertrand/DC/USEPA/US@EPA, Jonah Richmond/DC/USEPA/US@EPA  
Date: 10/01/2010 02:24 PM  
Subject: Settlement Agreement in Human Studies Rule Related Litigation

David -

As requested in your voicemail yesterday, here is a copy of the signed Settlement Agreement for the Human Studies Rule. I will get back to you on availability for scheduling the introductory briefing for the interagency reviewers. I just need to confirm availability of key staff. Thanks.

- Angela

[attachment "panna settlement agmt.pdf" deleted by Angela Hofmann/DC/USEPA/US]

Angela Hofmann

Director of Regulatory Coordination for Chemical

Safety and Pollution Prevention (OCSPP) U.S. Environmental Protection Agency (EPA)

Mailcode: 7101M

1200 Pennsylvania Ave., N.W., Washington, DC 20460

(Location: EPA East Building Room 3426 A) Phone number: 202-564-0258; Fax number: 202-564-0263

"Walsh, Heather V."  
<Heather\_V.\_Walsh@omb.eop  
.gov>

03/29/2010 07:38 PM

To Brenda Mallory

cc

bcc

Subject Out of Office AutoReply: EPA Settlement Agreement in  
Human Studies litigation - status?

I will be out of the office today (Monday, March 29), but will be checking email periodically. If you need to reach me immediately, please call my mobile number: (202) 236-4953. Thanks.